EPA Reg. No. 87583-5

PROCESSING REQUEST

Reg # 87583-5 **Decision # 516303**

Description: Label Amendment

Electronic Label & Letter (see PPLS):	OR	**Non Electronic Label & Letter** (Scanning required):
X Dated: 06/03/16		☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Karen M. Leavy

Division: AD

Phone: 308-6237 **Date: 06/08/16**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 2, 2016

Mr. Kevin Kutcel
Regulatory Agent for,
PureShield, Inc.
1445 Jupiter Park, Suite 11
Jupiter, FL 33458

Subject: Label Amendment – To update the product labeling
Product Name: Bio-Protect DP
EPA Registration Number: 87583-5
Application Date: April 11, 2016
Decision Number: 516303

Dear Mr. Kutcel:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Karen M. Leavy by phone at (703)-308-6237, or via email at Leavy.Karen@epa.gov.

Sincerely,

Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs
Date: June 2, 2016

Enclosure

ACCEPTED
06/02/2016
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 87583-5

BIO-PROTECT DP

DISINFECTANT and ANTIMICROBIAL AGENT
A Silicone Quaternary Ammonium Salt

Active Ingredients:	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride	35.60%
	n-alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride	6.40%
	Octyl decyl dimethyl ammonium chloride	4.80%
	Didecyl dimethyl ammonium chloride	2.88%
	Dioctyl dimethyl ammonium chloride	1.92%
Other Ingredients:		48.40%
TOTAL INGREDIENTS:		100.00%

Contains over 6% methanol

EPA Reg. No. 87583-5 **KEEP OUT OF REACH OF CHILDREN** EPA EST – XXXXX-XX-XX

DANGER [redacted] POISON

NET CONTENTS: 2, 4, 8, 16, 20, 22, OR 36 fluid oz.; 1, 5, 55, 150, or 300 gal. Lot No. _____

FIRST AID

Have the product container or label with you when calling the poison control center or doctor, or going for treatment.

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call poison control center or doctor for treatment advice.
- Methanol may cause blindness.

IF INHALED:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

IF ON SKIN:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER! Corrosive: Causes skin burns. Methanol may cause blindness. Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes, on skin, or on clothing. Avoid contact with skin. Avoid breathing spray mist. Wear protective eyewear (goggles or face shield) and protective clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing and wash before reuse.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame. De-activation of BIO-PROTECT DP can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of BIO-PROTECT DP.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

De-activation may be required during clean up if a spill occurs. De-activation of BIO-PROTECT DP can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of BIO-PROTECT DP.

DIRECTIONS FOR USE

For use in homes, offices, and institutions (schools, daycare centers, churches, correctional facilities)

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Allow treated areas and surfaces to dry before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application.

BIO-PROTECT DP is an effective disinfectant against *Salmonella enterica*, and *Staphylococcus aureus*. BIO-PROTECT DP is also effective against odor-causing bacteria, bacteria that causes staining and discoloration.

BIO-PROTECT DP may be used for treatment of the following hard non-porous surfaces to impart disinfection (*Salmonella enterica* and *Staphylococcus aureus*), bacteriostatic/fungistatic/algaestatic, and deodorizing activity:

	Pest controlled	Dilution Rate	Method of Application
Tubs, glazed tiles, vanity tops, shower stalls (areas), sinks, washable walls, vinyl wall paper for non-food contact, floors, window sills, cabinets, garbage cans, exterior surfaces of appliances and refrigerators	Odor-causing bacteria, bacteria which cause staining and discoloration, fungi *Salmonella enterica* and *Staphylococcus aureus*	0.5 oz/gallon	**SPRAY**: Dilute BIO-PROTECT DP in water; mix well. Using a trigger pump sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. **For Disinfecting:** Let stand for 10 minutes, then wipe surface dry.

BIO-PROTECT DP is an antimicrobial agent effective against microorganisms that cause offensive odors on hard, non-porous surfaces.
BIO-PROTECT DP is an antimicrobial agent effective against odor-causing bacteria in the kitchen and bathroom.
BIO-PROTECT DP is an antimicrobial agent that disinfects hard, non-porous surfaces and kills *Salmonella enterica* and *Staphylococcus aureus*.
BIO-PROTECT DP provides an invisible barrier to inhibit the growth of odor-causing bacteria.
BIO-PROTECT DP provides an invisible barrier to inhibit the growth of bacteria which cause staining and discoloration.
BIO-PROTECT DP prevents deterioration caused by bacteria.
BIO-PROTECT DP resists development of microbial odors.
BIO-PROTECT DP resists development of stains and discoloration due to bacteria.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

For Household/residential use packages:

Pesticide Storage: Store in original, tightly-closed containers in an area inaccessible to children or persons unfamiliar with its use. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original containers at or below 25 C (77F) and above 0 C (32F). Non-refillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

For Industrial and Commercial Use Packages:
Small Packages (1 gallon or less):
Pesticide Storage: Store in original, tightly-closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Store in original, unopened containers at or below 25 C (77F). This product has a minimum shelf life of 12 months after date of shipment.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling: Non-refillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Pails, Drums and IBC's (containers greater than one gallon)
Pesticide Storage: Store in original, tightly-closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Store in original, unopened containers at or below 25 C (77F). This product has a minimum shelf life of 12 months after date of shipment.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Containers Handling: REFILLABLE CONTAINER. Refill this container with this product only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill container ¼ full with water. Replace and tighten closure. Tip container in its side and roll it back and forth, ensuring at least one complete revolutions, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty rinsate into application equipment of mix tank or store for later use or disposal. Or pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use of disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING:

KRK Consulting LLC

5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
E-mail: kevinkutcel@gmail.com

April 11, 2016

US EPA (AMEND)
Office of Pesticide Programs
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Fast Track Amendment per California Department of Pesticide Regulation (EPA No. 87583-5)

In their review of the label, the California Department of Pesticide Regulation has requested that PureShield Inc. file an amendment with the US EPA with the following changes to the label:

- Correct the typographical error that occurred on latest stamped label dated 11/16/2015 in which the percent active ingredient was incorrectly changed to 36.60%. This amendment corrects the error and reports the percent active ingredient to be 35.60% which matches the CSF and now equals 100.00% for the Total Ingredients.

Please accept the application (8570-1) for this amendment and one copy of the label showing the highlighted change and three copies with the change.

Please note that KRK Consulting LLC is the authorized agent handling all correspondence for PureShield Inc. and therefore all responses should be directed to the contact information on the letterhead above.

Best Regards,

Kevin R. Kutcel,
Agent for PureShield Inc.

Please read instructions on reve... before completing form. Fo... Approved, OMB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
PureShield, Inc. / 87583-5	Eric Miederoff	[x] None [ ] Restricted
4. Company/Product (Name) PureShield, Inc. / Bio-Protect DP	**PM#** 31	

5. Name and Address of Applicant *(Include ZIP Code)*

PureShield Inc.
1445 Jupiter Park, Suite 11
Jupiter, FL 33458

[x] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [x] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Please see cover letter.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container		[x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [x] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Kevin Kutcel	Agent	440-263-7305

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
	Agent	Kevin R. Kutcel	Apr 11, 2016


Create/E... Collections Utilities ...ary T... Portal Help Exit
S: 984600
Milestone Email:
Regulatory Type: Product Registration - Section 3
Application Type: Amendment
Company: 87583 PURESHIELD, INC.
Fee For Service: Yes No
Billable: Yes No
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 31
Product #: 87583-5
Product Name: BIO-PROTECT DP
Me Too Section3: 53053-27
Me Too Product Name: AN 3651P
Application Date: 11-Apr-2016
Front End Date: 13-Apr-2016
FFS Due Date:
OPP Target Date:
OPP Rec'vd Date: 13-Apr-2016
Risk Manager Send Date: 14-Apr-2016
Negotiated Due Date:
Receipt Content
Paper Label
View/Edit
New Ingredient:
Receipt Description:
AMENDMENT

L

Fee for Service {984600x~

This package includes the following

- ○ New Registration
- ◉ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 31

Receipt No. S- 984600

EPA File Symbol/Reg. No. 87583-5

Pin-Punch Date: 4/13/2016

☑ This item is NOT subject to FFS action.

Action Code:

Requested: ____

Granted: ____

Amount Due: $ _____

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: Killian Date: 4-14-16

Remarks:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 14, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. KEVIN KUTCEL
KRK CONSULTING LLC
PURESHIELD, INC.
5807 CHURCHILL WAY
MEDINA, OH 44256-

PRODUCT NAME: BIO-PROTECT DP
COMPANY NAME: PURESHIELD, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 87583-5
EPA RECEIPT DATE: 04/13/16

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 31, at (703) 347-8028.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

PROCESSING REQUEST

Reg # 87583-5 **Decision # 511092**

Description: Amendment-to revise product labeling

Electronic Label & Letter (see PPLS):	OR	**Non Electronic Label & Letter** (Scanning required):
X Dated: 11/16/15		☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Karen Leavy

Division: AD

Phone: 308-6237 **Date: 11/24/15**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 16, 2015

Mr. Kevin Kutcel
Agent for PureShield Inc.
c/o PureShield Inc.
5807 Churchill Way
Medina, OH 44256

Subject: Label Amendment – to revise the product labeling as per California DPR's request to amend the precautionary language that correctly identifies the acute toxicity for Primary Skin
Product Name: Bio Protect DP
EPA Registration Number: 87583-5
Application Date: November 12, 2015
Decision Number: 511092

Dear Mr. Kutcel:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Karen M. Leavy by phone at (703)-308-6237, or via email at Leavy.Karen@epa.gov.

Sincerely,

Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs
Date: November 16, 2015

Enclosure

ACCEPTED
11/16/2015
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 87583-5

BIO-PROTECT DP

DISINFECTANT and ANTIMICROBIAL AGENT
A Silicone Quaternary Ammonium Salt

Active Ingredients:	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride	36.60%
	n-alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride	6.40%
	Octyl decyl dimethyl ammonium chloride	4.80%
	Didecyl dimethyl ammonium chloride	2.88%
	Dioctyl dimethyl ammonium chloride	1.92%
Other Ingredients:		48.40%
TOTAL INGREDIENTS:		100.00%

Contains over 6% methanol

EPA Reg. No. 87583-5 **KEEP OUT OF REACH OF CHILDREN** EPA EST – XXXXX-XX-XX

DANGER [redacted] POISON

NET CONTENTS: 2, 4, 8, 16, 20, 22, OR 36 fluid oz.; 1, 5, 55, 150, or 300 gal. Lot No. _____

FIRST AID

Have the product container or label with you when calling the poison control center or doctor, or going for treatment.

IF IN EYES:
- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call poison control center or doctor for treatment advice.
- Methanol may cause blindness.

IF INHALED:
- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

IF SWALLOWED:
- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

IF ON SKIN:
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER! Corrosive: Causes skin burns. Methanol may cause blindness. Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes, on skin, or on clothing. Avoid contact with skin. Avoid breathing spray mist. Wear protective eyewear (goggles or face shield) and protective clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing and wash before reuse.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame. De-activation of BIO-PROTECT DP can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of BIO-PROTECT DP.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

De-activation may be required during clean up if a spill occurs. De-activation of BIO-PROTECT DP can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of BIO-PROTECT DP.

DIRECTIONS FOR USE

For use in homes, offices, and institutions (schools, daycare centers, churches, correctional facilities)

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Allow treated areas and surfaces to dry before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application.

BIO-PROTECT DP is an effective disinfectant against *Salmonella enterica*, and *Staphylococcus aureus*. BIO-PROTECT DP is also effective against odor-causing bacteria, bacteria that causes staining and discoloration.

BIO-PROTECT DP may be used for treatment of the following hard non-porous surfaces to impart disinfection (*Salmonella enterica* and *Staphylococcus aureus*), bacteriostatic/fungistatic/algaestatic, and deodorizing activity:

	Pest controlled	Dilution Rate	Method of Application
Tubs, glazed tiles, vanity tops, shower stalls (areas), sinks, washable walls, vinyl wall paper for non-food contact, floors, window sills, cabinets, garbage cans, exterior surfaces of appliances and refrigerators	Odor-causing bacteria, bacteria which cause staining and discoloration, fungi *Salmonella enterica* and *Staphylococcus aureus*	0.5 oz/gallon	**SPRAY**: Dilute BIO-PROTECT DP in water; mix well. Using a trigger pump sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. **For Disinfecting:** Let stand for 10 minutes, then wipe surface dry.

BIO-PROTECT DP is an antimicrobial agent effective against microorganisms that cause offensive odors on hard, non-porous surfaces.
BIO-PROTECT DP is an antimicrobial agent effective against odor-causing bacteria in the kitchen and bathroom.
BIO-PROTECT DP is an antimicrobial agent that disinfects hard, non-porous surfaces and kills *Salmonella enterica* and *Staphylococcus aureus*.
BIO-PROTECT DP provides an invisible barrier to inhibit the growth of odor-causing bacteria.
BIO-PROTECT DP provides an invisible barrier to inhibit the growth of bacteria which cause staining and discoloration.
BIO-PROTECT DP prevents deterioration caused by bacteria.
BIO-PROTECT DP resists development of microbial odors.
BIO-PROTECT DP resists development of stains and discoloration due to bacteria.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

For Household/residential use packages:

Pesticide Storage: Store in original, tightly-closed containers in an area inaccessible to children or persons unfamiliar with its use. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original containers at or below 25 C (77F) and above 0 C (32F). Non-refillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

For Industrial and Commercial Use Packages:
Small Packages (1 gallon or less):
Pesticide Storage: Store in original, tightly-closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Store in original, unopened containers at or below 25 C (77F). This product has a minimum shelf life of 12 months after date of shipment.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling: Non-refillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Pails, Drums and IBC's (containers greater than one gallon)
Pesticide Storage: Store in original, tightly-closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Store in original, unopened containers at or below 25 C (77F). This product has a minimum shelf life of 12 months after date of shipment.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Containers Handling: REFILLABLE CONTAINER. Refill this container with this product only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill container ¼ full with water. Replace and tighten closure. Tip container in its side and roll it back and forth, ensuring at least one complete revolutions, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty rinsate into application equipment of mix tank or store for later use or disposal. Or pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use of disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING:

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
HUMAN HEALTH ASSESSMENT BRANCH
TOXICOLOGY STUDY EVALUATION WORKSHEET

I. STUDY IDENTIFICATION

Active Ingredient: 1. 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; 2. n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{16}) dimethyl benzyl ammonium chloride; 3. octyl decyl dimethyl ammonium chloride; 4. didecyl dimethyl ammonium chloride; 5. dioctyl dimethyl ammonium chloride
Formulated Product Name: AM 3651P
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5. 1710 **ID #:** 269397
Document #: 53139-0012 **Record #:** 283717
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Study Type: 811-Acute Oral Toxicity
Full Study Title: ACUTE ORAL TOXICITY STUDY IN RATS
Company Sponsor: BioShield Technologies, Inc., Norcross, GA
Conducting Laboratory: Stillmeadow, Inc., Sugar Land, TX
Final Report Date: 04/21/99
Study Interval: 1/13/99-3/10/99

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? -No
Is study acceptable? -Yes

- **Meets EPA guidelines**
- Yes - **Minor variances from guidelines**
- **Major variances from guidelines**
- **Could be upgraded with additional information (see VI-A)**

Yes - **Has useful data**
- **Insufficient data**
- **Non EPA validated study**
- **Other**_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?: no

C. ONE LINER-One or two sentence summary of the study:
53139-0012 283717; Acute oral toxicity; 811; Rat; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4850-98; 04/21/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered in a single dose by oral gavage to 15 males and 25 females. The rats were dosed in the following order and at the following dose levels (number dead/number treated in parentheses); at 5050 (5/5 F, 5/5 M), at 2000 (1/5 F, 3/5 M), at 3000 (3/5 F); at 1000 (2/5F, 0/5 M), and at 500 (0/5 F) mg/kg. Clinical observations: At 500 mg/kg dose level (5 females), all females survived exposure to the test substance; Body weight gain was unaffected by the administration of the test substance; All animals appeared normal for the duration of the study; The gross necropsy at the conclusion of the study revealed no observable abnormalities. At 1000, 2000, 3000 and 5050 mg/kg dose levels mortality was as follows: at 1000 mg/kg dose level (5/sex), 2 females died within 3 days of test substance administration; at 2000 mg/kg dose level (5/sex), three males and 1 female died within 5 days of test substance

administration; at 3000 mg/kg dose level (5 females), 3 females died within 6 days of test substance administration; at 5050 mg/kg dose level (5/sex), all animals died within 6 days of test substance administration. Prominent in-life observations for 1000, 2000, 3000 and 5050 mg/kg dose levels included alopecia (through day 14), activity decrease, anus red and swollen, crusted muzzle and eyes, diarrhea and soft feces, decreased defecation, respiratory chirp gurgle, piloerection, ptosis, polyuria, salivation, swollen face, sensitivity to touch, stained fur, withdrawn testes and walking on tiptoe, which were no longer evident in surviving animals by Day 13. Ataxia, nasal and ocular discharge, distended abdomen and gasping were observed only in animals that died on test. Body weight gain in surviving animals was largely unaffected by the administration of the test substance. One of seven males and three of nine females lost or failed to gain weight between days 0 and 7. The gross necropsy on animals that died on test revealed matted and stained fur; discolored lungs, spleen and liver; thickened stomach mucosa; gas and discolored contents in the gastrointestinal tract. The gross necropsy in animals surviving to termination of the study revealed no observable abnormalities, except alopecia in the genital area of three animals. LD50 (M/F) is > 500 mg/kg but < 2000 mg/kg; Toxicity Category III; **Study Acceptable.** (Mehta, 06/24/15)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?: Yes

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Staff Toxicologist **Date**

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Albino Rat
Strain: HSD: SD
Source of animals: Harlan Sprague Dawley, Inc., Indianapolis, IN
***Age at start:** Approximately 8 to 10 week old males and females; fasting weight of males 222-310 grams and of females 155-227 grams. Females were nulliparous and non-pregnant. Year of birth was mistyped as 1999 instead of 1998.
Route of administration: Oral, by gavage
Vehicle: none
Period of treatment: Single dose, 14-day observation period

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

Dosing Sequence	Dose Level (mg/kg)	Number of animals		Mortality (number dead/number treated)	
		Females	Males	Females	Males
1	5050	5	5	5/5	5/5
2	2000	5	5	1/5	3/5
3	3000	5	-	3/5	-
4	1000	5	5	2/5	0/5
5	500	5	-	0/5	-

IV. STUDY DESIGN AND EVALUATION

A. STUDY PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** AM 3651P; Composition: 55.2% total quaternary ammonium chloride; Batch#: B129828B-2 and B129828B-3. Physical properties: pale yellow liquid, date of received: 01/04/99 and 01/06/99, stored at room temperature. Expiration: 12/29/99.
*2. **Analysis of dosing material:** The test article was administered as received. Purity of test substance was provided as 55.2% total quaternary ammonium chloride. Records pertaining to identity, synthesis methods and location of documentation are the responsibility of the sponsor. A certificate of analysis specifying purity of test substance was not provided. Stability details were not provided. These are considered minor deficiencies and had no impact on study outcome.
3. **Animal selection:** OK
4. **Animal husbandry:** Animal room temperature and relative humidity ranges were maintained at 22±3°C and 30-70%, respectively.
5. **Mortality:** OK
6. **Number of animals:** OK
7. **Randomization of animals:** OK
8. **Dose level selection:** OK
9. **Route of administration:** the test material was administered by gastric intubation using a syringe and ball-tipped dosing needle.
10. **Exposure conditions:** OK
11. **Controls:** NA
12. **Observations:** Observations for mortality and clinical/behavioral signs of toxicity were made at least three times on the day of dosing (Day 0) and at least once daily thereafter for 14 days. Individual body weights were recorded just prior to dosing and on days 7 and 14, or at the time of discovery after death.
13. **Necropsies:** OK
14. **Appropriateness of methods:** OK; OECD test guidelines were followed in the current study, as recommended in US EPA OPPTS 870.1100 guidelines for acute oral toxicity testing.
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** GLP compliance statement and quality assurance audit record included in the report.
19. **Other:** NA

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED: At 500 mg/kg dose level (5 females), all females survived exposure to the test substance; Body weight gain was unaffected by the administration of the

test substance; All animals appeared normal for the duration of the study; The gross necropsy at the conclusion of the study revealed no observable abnormalities. At 1000, 2000, 3000 and 5050 mg/kg dose levels mortality was as follows: at 1000 mg/kg dose level (5/sex), 2 females died within 3 days of test substance administration; at 2000 mg/kg dose level (5/sex), three males and 1 female died within 5 days of test substance administration; at 3000 mg/kg dose level (5 females), 3 females died within 6 days of test substance administration; at 5050 mg/kg dose level (5/sex), all animals died within 6 days of test substance administration. Prominent in-life observations for 1000, 2000, 3000 and 5050 mg/kg dose levels included alopecia (through day 14), activity decrease, anus red and swollen, crusted muzzle and eyes, diarrhea and soft feces, decreased defecation, respiratory chirp gurgle, piloerection, ptosis, polyuria, salivation, swollen face, sensitivity to touch, stained fur, withdrawn testes and walking on tiptoe, which were no longer evident in surviving animals by Day 13. Ataxia, nasal and ocular discharge, distended abdomen and gasping were observed only in animals that died on test. Body weight gain in surviving animals was largely unaffected by the administration of the test substance. One of seven males and three of nine females lost or failed to gain weight between days 0 and 7. The gross necropsy on animals that died on test revealed matted and stained fur; discolored lungs, spleen and liver; thickened stomach mucosa; gas and discolored contents in the gastrointestinal tract. The gross necropsy in animals surviving to termination of the study revealed no observable abnormalities, except alopecia in the genital area of three animals.

B. ACUTE TOXICITY VALUE (LD50, LC50, etc.): LD50 (M/F) is > 500 mg/kg but < 2000 mg/kg

C. TOXICITY CATEGORY: III

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). What are they and can they be corrected with additional information? none **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? no **Are there any recommendations specific to this study?:** none

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
HUMAN HEALTH ASSESSMENT BRANCH
TOXICOLOGY STUDY EVALUATION WORKSHEET

I. STUDY IDENTIFICATION

Active Ingredient: 1. 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; 2. n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{16}) dimethyl benzyl ammonium chloride; 3. octyl decyl dimethyl ammonium chloride; 4. didecyl dimethyl ammonium chloride; 5. dioctyl dimethyl ammonium chloride
Formulated Product Name: AM 3651P
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5. 1710 **ID #:** 269397
Document #: 53139-0013 **Record #:** 283718
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Full Study Title: ACUTE DERMAL TOXICITY STUDY IN RABBITS
Company Sponsor: BioShield Technologies, Inc., Norcross, GA
Conducting Laboratory: Stillmeadow, Inc., Sugar Land, TX
Final Report Date: 04/21/99
Study Interval: 1/07/99-3/04/99

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? -No
Is study acceptable? -No

- **Meets EPA guidelines**
- **Minor variances from guidelines**
Yes - **Major variances from guidelines**
No - **Could be upgraded with additional information (see VI-A)**

Yes - **Has useful data**
- **Insufficient data**
- **Non EPA validated study**
- **Other**_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?: no

C. ONE LINER-One or two sentence summary of the study:
53139-0013 283718; Acute dermal toxicity; 812; Rabbit; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4851-98; 04/21/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered to 5 males and 20 female rabbits. The rabbits were dosed at 5050 (5/sex), 5500 (5 F), 3500 (5 F), and 500 (5 F) mg/kg dose levels, 24-hour exposure, occlusive wrap. Clinical observations: At 500 mg/kg dose level (5 females), all females survived exposure to the test substance; Body weight gain was unaffected by the administration of the test substance; All animals appeared normal for the duration of the study; The gross necropsy at the conclusion of the study revealed no observable abnormalities. At 3500 (5 females) and at 5050 (5/sex) mg/kg dose level, two female deaths were noted at each dose level. At 5500 mg/kg dose level (5 females), no mortality was noted. Prominent in-life observations for 3500, 5050 and 5500 mg/kg dose levels included diarrhea and soft feces, decreased and no defecation, and not

eating. Surviving animals were asymptomatic by Day 4, except for one animal with decreased defecation on Day 12. Dermal irritation in animals at all dose levels included very slight to severe erythema, very slight to moderate edema, atonia, coriaceousness, desquamation, eschar and/or necrosis. Body weight gain in several surviving animals was affected by the administration of the test substance. Four of five males and six of eleven females lost or failed to gain weight between Days 0 and 7. Gross necropsy in animals that died on test revealed ocular and nasal discharge, hemorrhage around eye, discolored abdominal skin, lungs discolored and having lesions, stomach wall and liver friable; fluid in the abdomen and gas in the intestines. Gross necropsy in animals surviving to termination of the study revealed no observable abnormalities. There were two female deaths each at 3500 and 5050 mg/kg dose levels, and no deaths at 5500 mg/kg dose level. Hence, a dose response relationship for females was not established; Study Unacceptable, Not Upgradable. (Mehta, 06/26/15)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?: No

Staff Toxicologist **Date**

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Albino Rabbit
Strain: New Zealand white
Source of animals: Ray Nichols Rabbitry, Lumberton, TX
Age at start: Approximately 16 week old; 5 males and 20 females; Females were nulliparous and non-pregnant; Males weighing 2300-2900 grams and females weighing 2075-3350 grams on day of dosing.
Route of administration: Dermal application
Vehicle: none: test article was used as received
Period of treatment: 24-hour exposure, 14-day observation period

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

Dosing Sequence	Dose Level (mg/kg)	Number of animals		Mortality (number dead/number treated)	
		Females	Males	Females	Males
1	5050	5	5	2/5	0/5
2	5500	5	-	0	-
2	3500	5	-	2/5	-
3	500	5	-	0/5	-

IV. STUDY DESIGN AND EVALUATION

A. STUDY PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** AM 3651P; Composition: 55.2% total quaternary ammonium chloride; Batch#: B129828B-2 and B129828B-3. Physical properties: pale yellow liquid, date of received: 01/04/99 and 01/06/99, stored at room temperature. Expiration: 12/29/99.

*2. **Analysis of dosing material:** The test article was applied as received. Purity of test substance was provided as 55.2% total quaternary ammonium chloride. Records pertaining to identity, synthesis methods and location of documentation are the responsibility of the sponsor. A certificate of analysis specifying purity of test substance was not provided. Stability details were not provided. These are considered minor deficiencies and had no impact on study outcome.

3. **Animal selection:** OK
4. **Animal husbandry:** Animal room temperature and relative humidity ranges were maintained at 22±3°C and 30-70%, respectively.
5. **Mortality:** OK
6. **Number of animals:** OK
7. **Randomization of animals:** OK
8. **Dose level selection:** OK
9. **Route of administration:** OK; Dermal
10. **Exposure conditions:** OK
11. **Controls:** NA
12. **Observations:** Animals were observed for mortality and clinical/behavioral signs of toxicity at least three times on day of dosing (Day 0) and at least once daily thereafter for 14 days; body weights were recorded prior to dosing and on day 7 and 14, or at the time of discovery after death. Observations for evidence of dermal irritation were made at approximately 60 minutes after removal of wrappings, and on days 4, 7, 11 and 14.
13. **Necropsies:** OK
14. **Appropriateness of methods:** OK

*15. **Treatment of results:** There were two female deaths each at 3500 and 5050 mg/kg dose levels, and no deaths at 5500 mg/kg dose level. Hence, a dose response relationship for females was not established. This is considered a major deficiency and will have an impact on study outcome (see section VI.A)

*16. **Test report:** on page # 14, the 5500 dose level is mistyped as 5550 mg/kg. This is considered a minor deficiency and had no impact on study outcome.

17. **Consistency:** OK
18. **Good Laboratory Practice:** GLP compliance statement and quality assurance audit record included in the report.
19. **Other:** NA

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED: At 500 mg/kg dose level (5 females), all females survived exposure to the test substance; Body weight gain was unaffected by the administration of the test substance; All animals appeared normal for the duration of the study; The gross necropsy at the conclusion of the study revealed no observable abnormalities. At 3500 (5 females) and at 5050 (5/sex) mg/kg dose level, two female deaths were noted at each dose level. At 5500 mg/kg dose level (5 females), no mortality was noted. Prominent in-life observations for 3500, 5050 and 5500 mg/kg dose levels included diarrhea and soft feces, decreased and no defecation, and not eating. Surviving animals were asymptomatic by Day 4, except for one animal with decreased defecation on Day 12. Dermal irritation in animals at all dose levels included very slight to severe erythema, very slight to moderate edema, atonia, coriaceousness, desquamation, eschar and/or necrosis. Body weight gain in several surviving animals was affected by the administration of the test substance. Four of five males and six of eleven females lost or failed to gain weight between Days 0 and 7. Gross necropsy in animals that died on test revealed ocular and nasal discharge, hemorrhage around eye, discolored abdominal skin, lungs discolored and having lesions, stomach wall and liver friable; fluid in the abdomen and gas in the intestines. Gross necropsy in animals surviving to termination of the study revealed no observable abnormalities.

B. ACUTE TOXICITY VALUE (LD50, LC50, etc.): Not established

C. TOXICITY CATEGORY: II (see section VI)

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). What are they and can they be corrected with additional information? Yes **Be specific:** although, there were no female mortalities at 5500 mg/kg dose level, there were two female deaths each at 3500 and at 5050 mg/kg dose levels. Therefore, a dose response relationship could not be established. This is considered a major deficiency. The study is unacceptable and not upgradable.

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? no **Are there any recommendations specific to this study?:** Although unacceptable and not upgradable, study supports Toxicity Category II acute dermal toxicity.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
HUMAN HEALTH ASSESSMENT BRANCH
TOXICOLOGY STUDY EVALUATION WORKSHEET

I. STUDY IDENTIFICATION

Active Ingredient: 1. 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; 2. n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{16}) dimethyl benzyl ammonium chloride; 3. octyl decyl dimethyl ammonium chloride; 4. didecyl dimethyl ammonium chloride; 5. dioctyl dimethyl ammonium chloride
Formulated Product Name: AM 3651P
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5. 1710 **ID #:** 269397
Document #: 53139-0014 **Record #:** 283719
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Study Type: 813-Acute Inhalation Toxicity
Full Study Title: ACUTE INHALATION TOXICITY STUDY IN RATS
Company Sponsor: BioShield Technologies, Inc., Norcross, GA
Conducting Laboratory: Stillmeadow, Inc., Sugar Land, TX
Final Report Date: 04/26/99
Study Interval: 01/14/99-02/09/99

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? -No
Is study acceptable? -Yes

- **Meets EPA guidelines**
- Yes - **Minor variances from guidelines**
- **Major variances from guidelines**
- **Could be upgraded with additional information (see VI-A)**

Yes - **Has useful data**
- **Insufficient data**
- **Non EPA validated study**
- **Other**_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?: No

C. ONE LINER-One or two sentence summary of the study:
53139-0014 283719; Acute inhalation toxicity; 813; Rat; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4852-98; 04/26/99; Bennick, J. E., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered to 5 animals/sex at 3.19 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 2.7 µm (3.15); 5 animals/sex at 1.42 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 2.3 µm (7.3); 5 animals/sex at 0.95 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 3.6 µm (4.25); 5 males at 0.72 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 1.5 µm (3.6), 4-hour nose-only exposure. Clinical observation: Mortality at each dose level was as follows (number dead/number treated in parenthesis): at 0.72 mg/L (1/5 males), at 0.95 mg/L (2/5 males, 1/5 females), at 1.42 mg/L (4/5 males, 2/5 females), and at 3.19 mg/L (3/5 males, 3/5 females).

Prominent in-life observations included aggression, crusted eyes/nose, decreased defecation, gasping, piloerection, ptosis and sensitivity to touch, which were no longer evident in surviving animals by day 8. Activity decreases and respiratory gurgle were observed through Day 14. Discolored eye, polyuria and withdrawn testes were observed only in one animal that died on test. Abnormal necropsy findings in animals that died on test pertained to crusted eyes/nose/mouth; discolored and swollen lungs, discolored stomach and contents, and gas in the gastrointestinal tract. The gross necropsy conducted on each animal surviving to termination of the study revealed no observable abnormalities, except discolored lungs in three animals. LC50 (M) is 1.32 mg/L with 95% confidence interval of 0.53 to 3.35 mg/L, and LC50 (F) is 2.24 mg/L with 95% confidence interval of 0.97 to 5.20 mg/L; Toxicity Category III; Study Acceptable. (Mehta, 06/29/15)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?: Yes

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Staff Toxicologist **Date**

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Rat
Strain: HSD: Sprague-Dawley
Source of animals: Harlan Sprague Dawley, Inc., Indianapolis, IN
Age at start: Approximately 8 weeks old; Sex: 20 males and 15 females; Weight: males weighing 237-354 grams and females weighing 181-228 grams on day of dosing. Females were nulliparous and non-pregnant.
Route of administration: Inhalation, nose-only exposure
Vehicle: none
Period of treatment: 4-hour exposure, 14-day observation period

B. BACKGROUND (including relationship of this study to other studies): Trial assays were conducted to determine methods of aerosolizing the test substance into the exposure chamber to produce an acceptable concentration and mass median aerodynamic diameter (MMAD).

C. TREATMENT LEVELS AND GROUP SIZE:

Dosing Sequence	Dose Level (mg/L)	Number of animals		Mortality (number dead/number treated)	
		Females	Males	Females	Males
1	3.19	5	5	3/5	3/5
2	1.42	5	5	2/5	4/5
3	0.95	5	5	1/5	2/5
4	0.72	-	5	-	1/5

IV. STUDY DESIGN AND EVALUATION

A. STUDY PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

*1. **Test article:** AM 3651P; Composition: 55.2% total quaternary ammonium chloride; Batch#: B129828B-2 and B129828B-3. Physical properties: pale yellow liquid, date of received: 01/04/99 and 01/06/99, stored at room temperature. Expiration: 12/29/99. The test article was applied as received. Purity of test substance was provided as 55.2% total quaternary ammonium chloride. Records pertaining to identity, synthesis methods and location of documentation are the responsibility of the sponsor. A certificate of analysis specifying purity of test substance was not provided. Stability details were not provided. These are considered minor deficiencies and had no impact on study outcome.
2. **Analysis of dosing material:** The animals were exposed to an aerosol generated from undiluted liquid test substance. The concentration of the test substance in the exposure atmosphere was determined gravimetrically twice per hour and nominally at the end of the exposure. The gravimetric concentration was determined by passing a known volume of exposure air through a pre-weighed filter and dividing the amount of test substance deposited on the filter by the volume of air that passed through the filter. A cascade impactor was used to assess the particle size distribution of the test atmosphere by withdrawing samples from the breathing zone of the animals at two intervals. The collections were carried out for 30 seconds at airflows of 7.3 Lpm.
3. **Animal selection:** OK
4. **Animal husbandry:** Animal room temperature and relative humidity ranges were maintained at 22±3°C and 30-70%, respectively.
5. **Mortality:** OK
6. **Number of animals:** OK
7. **Randomization of animals:** OK
8. **Dose level selection:** OK
9. **Route of administration:** OK
10. **Exposure conditions:** A 500 L nose-only stainless steel, dynamic flow inhalation chamber was utilized in this study. 5 animals/sex at 3.19 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 2.7 µm (3.15); 5 animals/sex at 1.42 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 2.3 µm (7.3); 5 animals/sex at 0.95 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 3.6 µm (4.25); 5 males at 0.72 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 1.5 µm (3.6), 4-hour nose-only exposure.
11. **Controls:** NA
12. **Observations:** Animals were observed frequently for pharmacological and /or toxicological effects on the day of dosing (Day 0) and at least once daily thereafter for 14 Days; individual body weights were recorded just prior to inhalation exposure and on Days 7 and 14. On Day 14 post-exposure, all animals were subjected to gross necropsy.
13. **Necropsies:** OK
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK

16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** GLP compliance statement and quality assurance audit records were included in the report.
19. **Other:** NA

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED: Mortality at each dose level was as follows (number dead/number treated in parenthesis): at 0.72 mg/L (1/5 males), at 0.95 mg/L (2/5 males, 1/5 females), at 1.42 mg/L (4/5 males, 2/5 females), and at 3.19 mg/L (3/5 males, 3/5 females). Prominent in-life observations included aggression, crusted eyes/nose, decreased defecation, gasping, piloerection, ptosis and sensitivity to touch, which were no longer evident in surviving animals by day 8. Activity decreases and respiratory gurgle were observed through Day 14. Discolored eye, polyuria and withdrawn testes were observed only in one animal that died on test. Abnormal necropsy findings in animals that died on test pertained to crusted eyes/nose/mouth; discolored and swollen lungs, discolored stomach and contents, and gas in the gastrointestinal tract. The gross necropsy conducted on each animal surviving to termination of the study revealed no observable abnormalities, except discolored lungs in three animals.

B. ACUTE TOXICITY VALUE (LD50, LC50, etc.): LC50 (M) is 1.32 mg/L with 95% confidence interval of 0.53 to 3.35 mg/L, and LC50 (F) is 2.24 mg/L with 95% confidence interval of 0.97 to 5.20 mg/L.

C. TOXICITY CATEGORY: III

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). What are they and can they be corrected with additional information? none **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? no **Are there any recommendations specific to this study?:** none

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
HUMAN HEALTH ASSESSMENT BRANCH
TOXICOLOGY STUDY EVALUATION WORKSHEET

I. STUDY IDENTIFICATION

Active Ingredient: 1. 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; 2. n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{16}) dimethyl benzyl ammonium chloride; 3. octyl decyl dimethyl ammonium chloride; 4. didecyl dimethyl ammonium chloride; 5. dioctyl dimethyl ammonium chloride
Formulated Product Name: AM 3651P
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5. 1710 **ID #:** 269397
Document #: 53139-0015 **Record #:** 283720
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Study Type: 814-Primary Eye Irritation
Full Study Title: PRIMARY EYE IRRITATION STUDY IN RABBITS
Company Sponsor: BioShield Technologies, Inc., Norcross, GA
Conducting Laboratory: Stillmeadow, Inc., Sugar Land, TX
Final Report Date: 03/31/99
Study Interval: 01/11/99-02/01/99

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? -No
Is study acceptable? -Yes

- **Meets EPA guidelines**
- Yes - **Minor variances from guidelines**
- **Major variances from guidelines**
- **Could be upgraded with additional information (see VI-A)**

Yes - **Has useful data**
- **Insufficient data**
- **Non EPA validated study**
- **Other**_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?: Yes; Category I eye irritant

C. ONE LINER-One or two sentence summary of the study:
53139-0015 283720; Acute Eye Irritation; 814; Rabbit; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4853-98; 03/31/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered to 3 male and 6 female (3 unwashed and 3 washed) rabbits by ocular instillation, Dose: 0.1 ml in the right eye. Observations: For unwashed eyes, "positive" effects persisted through Day 21 post-instillation. One animal/sex exhibited pain (squealing) at the time of treatment. Opacity: from 24 hours to day 21 post-instillation 6/6 treated eyes couldn't be scored due to chemosis and/or discharge. Conjunctival redness: on day 21, 2/6 treated eyes showed score 2 redness and 4/6 treated eyes couldn't be scored due to chemosis and/or discharge; in addition, 5/6 animals showed moderate and 1/6 animals showed severe alopecia around the eye. Chemosis: on day 21 post-instillation, 3/6 treated eyes had score 3, 2/6

treated eyes had score 2, and 1/6 treated eyes had score 4 chemosis. Discharge: on day 21 post-instillation, 5/6 treated eyes showed score 2, and 1/6 treated eyes showed score 3 discharge. Necrosis was evident in 6/6 treated eyes up to 24 hours post-instillation. For washed eyes, "positive" effects persisted through Day 21 post-instillation. Opacity: on day 21 post-instillation, 1/3 treated eyes showed score 4 opacity, with apparent invasion of cornea by blood vessels, and 2/3 treated eyes couldn't be scored due to chemosis and/or discharge. Conjuctival redness: on day 21 post-instillation, 2/3 treated eyes showed score 3, and 1/3 treated eyes showed score 2 redness; moderate alopecia around the eye was noted for one treated eye. Chemosis: at 21 days post-instillation, 1/3 treated eyes showed score 3, and 2/3 treated eyes showed score 2 chemosis. Discharge: at 21 days post-instillation, 3/3 treated eyes showed score 2 discharge. Toxicity Category I; Study Acceptable. (Mehta, 06/30/15)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?: Yes

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Staff Toxicologist **Date**

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Rabbit
Strain: New Zealand White
Source of animals: Ray Nichols Rabbitry, Lumberton, TX
Age at start: Young adult, approximately 15 week old, Sex: 3 males and 3 females (unwashed); 3 females (washed); males weighing: 2275-2975 grams and females weighing 2275-2725 grams.
Route of administration: Ocular instillation
Vehicle: none
Period of treatment: Single dose, 72-hour observation period

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

	Units (0.1 ml/eye)
#Males:	3 (unwashed)
#Females:	6 (3 unwashed and 3 washed)

IV. STUDY DESIGN AND EVALUATION

A. STUDY PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** AM 3651P; Composition: 55.2% total quaternary ammonium chloride; Batch#: B129828B-2 and B129828B-3. Physical properties: pale yellow liquid, date of

received: 01/04/99 and 01/06/99, stored at room temperature. pH: 6.96. Expiration: 12/29/99.

*2. **Analysis of dosing material:** The undiluted test article was instilled as received. Purity of test substance was provided as 55.2% total quaternary ammonium chloride. Records pertaining to identity, synthesis methods and location of documentation are the responsibility of the sponsor. A certificate of analysis specifying purity of test substance was not provided. Stability details were not provided. These are considered minor deficiencies and had no impact on study outcome.
3. **Animal selection:** OK
4. **Animal husbandry:** Animal room temperature and relative humidity ranges were maintained at 20±3°C and 30-70%, respectively.
5. **Mortality:** NA
6. **Number of animals:** OK
7. **Randomization of animals:** Both eyes of each animal were determined to be free of defects prior to inclusion of the animal in the study.
8. **Dose level selection:** OK; On Day 0, a dose of 0.1 mL of the undiluted test substance was placed into the conjuctival sac of the right eye. Three of the treated eyes ("washed eyes") were each washed with room temperature deionized water for one minute beginning 30 seconds after treatment.
9. **Route of administration:** OK
10. **Exposure conditions:** OK
11. **Controls:** Contralateral eye
12. **Observations:** Ocular irritation scores were recorded at 1, 24, 48 and 72 hours and at 4, 7, 10, 14, 17 and 21 days post-instillation.
13. **Necropsies:** NA
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** GLP compliance statement and quality assurance audit record included in the report.
19. **Other:** NA

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED: <u>For unwashed eyes,</u> "positive" effects persisted through Day 21 post-instillation. One animal/sex exhibited pain (squealing) at the time of treatment. Opacity: from 24 hours to day 21 post-instillation 6/6 treated eyes couldn't be scored due to chemosis and/or discharge. Conjunctival redness: on day 21, 2/6 treated eyes showed score 2 redness and 4/6 treated eyes couldn't be scored due to chemosis and/or discharge; in addition, 5/6 animals showed moderate and 1/6 animals showed severe alopecia around the eye. Chemosis: on day 21 post-instillation, 3/6 treated eyes had score 3, 2/6 treated eyes had score 2, and 1/6 treated eyes had score 4 chemosis. Discharge: on day 21 post-instillation, 5/6 treated eyes showed score 2, and 1/6 treated eyes showed score 3 discharge. Necrosis was

evident in 6/6 treated eyes up to 24 hours post-instillation. For washed eyes, "positive" effects persisted through Day 21 post-instillation. Opacity: on day 21 post-instillation, 1/3 treated eyes showed score 4 opacity, with apparent invasion of cornea by blood vessels, and 2/3 treated eyes couldn't be scored due to chemosis and/or discharge. Conjuctival redness: on day 21 post-instillation, 2/3 treated eyes showed score 3, and 1/3 treated eyes showed score 2 redness; moderate alopecia around the eye was noted for one treated eye. Chemosis: at 21 days post-instillation, 1/3 treated eyes showed score 3, and 2/3 treated eyes showed score 2 chemosis. Discharge: at 21 days post-instillation, 3/3 treated eyes showed score 2 discharge.

B. ACUTE TOXICITY VALUE (LD50, LC50, etc.): NA

C. TOXICITY CATEGORY: I

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). What are they and can they be corrected with additional information? None **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? Yes; Toxicity Category I eye irritant **Are there any recommendations specific to this study?:** None

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
HUMAN HEALTH ASSESSMENT BRANCH
TOXICOLOGY STUDY EVALUATION WORKSHEET

I. STUDY IDENTIFICATION

Active Ingredient: 1. 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; 2. n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{16}) dimethyl benzyl ammonium chloride; 3. octyl decyl dimethyl ammonium chloride; 4. didecyl dimethyl ammonium chloride; 5. dioctyl dimethyl ammonium chloride
Formulated Product Name: AM 3651P
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5.1710 **ID #:** 269397
Document #: 53139-0016 **Record #:** 283721
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Study Type: 815; PRIMARY DERMAL IRRITATION STUDY IN RABBITS
Full Study Title: ACUTE DERMAL IRRITATION IN RABBITS
Company Sponsor: BioShield Technologies, Inc., Norcross, GA
Conducting Laboratory: Stillmeadow, Inc., Sugar Land, TX
Final Report Date: 03/31/99
Study Interval: 01/12/99-01/26/99

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? -No
Is study acceptable? -Yes

- **Meets EPA guidelines**
Yes - **Minor variances from guidelines**
- **Major variances from guidelines**
- **Could be upgraded with additional information (see VI-A)**

Yes - **Has useful data**
- **Insufficient data**
- **Non EPA validated study**
- **Other**_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?: No

C. ONE LINER-One or two sentence summary of the study:
53139-0016 283721; Acute Dermal Irritation Study; 815; Rabbits; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4854-98; 03/31/99; Kuhn, J.O., The skin of 3 males and 3 female New Zealand albino rabbits was exposed to 0.5 ml of AM 3651P (a.i.: 55.2% total quaternary ammonium chloride)/site, one site/animal, for 4 hours under a semi-occlusive wrap. Erythema: at 1 hour post-application, 5/6 animals showed score 2, and 1/6 animals showed score 1 erythema; from 24 hours to day 7 post-application 6/6 treated sites showed score 2 erythema; day 10 post-application, 5/6 sites showed score 2 and 1/6 treated sites showed score 1 erythema; day 14 post-application, 2/6 treated sites showed score 4, 2/6 sites showed score 2, and 2/6 sites showed score 1 erythema. Edema: at 1 hour post-application, 3/6 rabbits showed score 1, 2/6 sites showed score 2, and 1/6 sites showed score 3 edema; at 24 hours post-application, 3/6 sites showed score 1, and 3/6 sites showed score 2 edema; at 48 and at 72 hours post-application, 5/6 sites showed score 1 edema; at day 7 and at day 10 post-application, 3/6 sites showed score 1

edema; at day 14 post-application, 1/6 rabbits showed score 1 edema. **Toxicity Category I** (severe erythema (score 4) persisted up to study termination); Study Acceptable. (Mehta, 06/30/15)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?: Yes

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Staff Toxicologist **Date**

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Albino Rabbit
Strain: New Zealand White
Source of animals: Ray Nichols Rabbitry, Lumberton, TX
Age at start: Young adult approximately 12 week old; Sex: 3 males and 3 females; Males weighing: 2550-3000 grams and females weighing 2550-3100 grams.
Route of administration: Dermal application
Vehicle: none
Period of treatment: 4-hour exposure, 72-hour observation period

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

	Units (0.5 ml/site)
#Males:	3
#Female:	3

IV. STUDY DESIGN AND EVALUATION

A. STUDY PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** AM 3651P; Composition: 55.2% total quaternary ammonium chloride; Batch#: B129828B-2 and B129828B-3. Physical properties: pale yellow liquid, date of received: 01/04/99 and 01/06/99, stored at room temperature. pH: 6.96. Expiration: 12/29/99.
*2. **Analysis of dosing material:** The undiluted test article was applied as received. Purity of test substance was provided as 55.2% total quaternary ammonium chloride. Records pertaining to identity, synthesis methods and location of documentation are the responsibility of the sponsor. A certificate of analysis specifying purity of test substance was not provided. Stability details were not provided. These are considered minor deficiencies and had no impact on study outcome.
3. **Animal selection:** OK
4. **Animal husbandry:** Animal room temperature and relative humidity ranges were maintained at 20±3°C and 30-70%, respectively.
5. **Mortality:** NA

TO: Teresa Coe, Environmental Scientist
Pesticide Registration Branch

FROM: Human Health Assessment Branch **Date:** 07/02/15

PRODUCT REGISTRATION RECOMMENDATION SHEET

Formulated Product Name: XMICROBE DP
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5.1710 **ID #:** 269397
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Document #: 53139-0012 thru -0017
Company Name: Xmicrobe, LLC., Clackamas, OR

RECOMMENDATION:

Submitted for a Section 3 Registration.

The data reviewed are adequate for a complete acute toxicological evaluation.

The product label does not adequately identify the Toxicity Category I primary skin irritation hazard and the Toxicity category II acute dermal toxicity hazard indicated by the data reviewed (see note below).*

The First Aid statements are adequate with regard to the assigned acute toxicity categories.

Registration is not recommended at this time.

* Note: adding precautionary language for toxicity category I primary skin irritation hazard precludes the need for acute dermal toxicity category II precautionary language.

Staff Toxicologist **Date**

TO--File: Registration **Environmental Scientist:** Teresa Coe
Branch: Registration

FROM—Human Health Assessment

DATA PACKAGE SUMMARY AND RECOMMENDATION SHEET

Active Ingredient: 1. 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; 2. n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{18}) dimethyl benzyl ammonium chloride; 3. octyl decyl dimethyl ammonium chloride; 4. didecyl dimethyl ammonium chloride; 5. dioctyl dimethyl ammonium chloride
Formulated Product Name: Xmicrobe DP
Formulation: active ingredient: 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride 35.60%; n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{18}) dimethyl benzyl ammonium chloride 6.40%; octyl decyl dimethyl ammonium chloride 4.80%; didecyl dimethyl ammonium chloride 2.88%; dioctyl dimethyl ammonium chloride 1.92%; inert ingredients: 48.40%*
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5.1710 **ID #:** 269397
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Document #: 53139-0012 thru -0017
Company Name: Xmicrobe, LLC., Clackamas, OR
* Contains over 6% methanol

SUMMARY ("One-liners" from each study worksheet, significant information not mentioned in worksheets, other pertinent information for ongoing review of registration. Attach additional sheets if needed):

The Environmental Scientist cited data contained in data volumes 53139-0012 thru -0017 to support registration of the subject product.

The differences in formulation between the test article and the subject product are of minimal toxicological concern. The acute toxicity studies are suitable for bridging to the subject product.

AM 3651P (a.i.: 55.2% total quaternary ammonium chloride)
- Acute Toxicity Categories

Acute Oral Toxicity (LD_{50})	III
Acute Dermal Toxicity (LD_{50})	Study Unacceptable*
Acute Inhalation Toxicity (LC_{50})	III
Primary Eye Irritation	I
Primary Dermal Irritation	I
Dermal Sensitization	Negative for dermal sensitization

*See Conclusions

AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) - Acute Toxicity Studies

Acute Oral Toxicity (LD_{50})

53139-0012 283717; Acute oral toxicity; 811; Rat; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4850-98; 04/21/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered in a single dose by oral gavage to 15 males and 25 females. The rats were dosed in the following order and at the following dose levels (number dead/number treated in parentheses); at 5050 (5/5 F, 5/5 M), at 2000 (1/5 F, 3/5 M), at 3000 (3/5 F); at 1000 (2/5F, 0/5 M), and at 500 (0/5 F) mg/kg. Clinical observations: At 500 mg/kg dose level (5 females), all females survived exposure to the test substance; Body weight gain was unaffected by the administration of the test substance; All animals appeared normal for the duration of the study; The gross necropsy at the conclusion of the study revealed no observable abnormalities. At 1000, 2000, 3000 and 5050 mg/kg dose levels mortality was as follows: at 1000 mg/kg dose level (5/sex), 2 females died within 3 days of test substance administration; at 2000 mg/kg dose level (5/sex), three males and 1 female died within 5 days of test substance administration; at 3000 mg/kg dose level (5 females), 3 females died within 6 days of test substance administration; at 5050 mg/kg dose level (5/sex), all animals died within 6 days of test substance administration. Prominent in-life observations for 1000, 2000, 3000 and 5050 mg/kg dose levels included alopecia (through day 14), activity decrease, anus red and swollen, crusted muzzle and eyes, diarrhea and soft feces, decreased defecation, respiratory chirp gurgle, piloerection, ptosis, polyuria, salivation, swollen face, sensitivity to touch, stained fur, withdrawn testes and walking on tiptoe, which were no longer evident in surviving animals by Day 13. Ataxia, nasal and ocular discharge, distended abdomen and gasping were observed only in animals that died on test. Body weight gain in surviving animals was largely unaffected by the administration of the test substance. One of seven males and three of nine females lost or failed to gain weight between days 0 and 7. The gross necropsy on animals that died on test revealed matted and stained fur; discolored lungs, spleen and liver; thickened stomach mucosa; gas and discolored contents in the gastrointestinal tract. The gross necropsy in animals surviving to termination of the study revealed no observable abnormalities, except alopecia in the genital area of three animals. LD50 (M/F) is > 500 mg/kg but < 2000 mg/kg; Toxicity Category III; **Study Acceptable**. (Mehta, 06/24/15)

Acute Dermal Toxicity (LD_{50})

53139-0013 283718; Acute dermal toxicity; 812; Rabbit; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4851-98; 04/21/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered to 5 males and 20 female rabbits. The rabbits were dosed at 5050 (5/sex), 5500 (5 F), 3500 (5 F), and 500 (5 F) mg/kg dose levels, 24-hour exposure, occlusive wrap. Clinical observations: At 500 mg/kg dose level (5 females), all females survived exposure to the test substance; Body weight gain was unaffected by the administration of the test substance; All animals appeared normal for the duration of the study; The gross necropsy at the conclusion of the study revealed no observable abnormalities. At 3500 (5 females) and at 5050 (5/sex) mg/kg dose level, two female deaths were noted at each dose level. At 5500 mg/kg dose level (5 females), no mortality was noted. Prominent in-life observations for 3500, 5050 and 5500 mg/kg dose levels included diarrhea and soft feces, decreased and no defecation, and not

eating. Surviving animals were asymptomatic by Day 4, except for one animal with decreased defecation on Day 12. Dermal irritation in animals at all dose levels included very slight to severe erythema, very slight to moderate edema, atonia, coriaceousness, desquamation, eschar and/or necrosis. Body weight gain in several surviving animals was affected by the administration of the test substance. Four of five males and six of eleven females lost or failed to gain weight between Days 0 and 7. Gross necropsy in animals that died on test revealed ocular and nasal discharge, hemorrhage around eye, discolored abdominal skin, lungs discolored and having lesions, stomach wall and liver friable; fluid in the abdomen and gas in the intestines. Gross necropsy in animals surviving to termination of the study revealed no observable abnormalities. There were two female deaths each at 3500 and 5050 mg/kg dose levels, and no deaths at 5500 mg/kg dose level. Hence, a dose response relationship for females was not established; Study Unacceptable, Not Upgradable. (Mehta, 06/26/15)

Acute Inhalation Toxicity (LC_{50})

53139-0014 283719; Acute inhalation toxicity; 813; Rat; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4852-98; 04/26/99; Bennick, J. E., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered to 5 animals/sex at 3.19 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 2.7 µm (3.15); 5 animals/sex at 1.42 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 2.3 µm (7.3); 5 animals/sex at 0.95 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 3.6 µm (4.25); 5 males at 0.72 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 1.5 µm (3.6), 4-hour nose-only exposure. Clinical observation: Mortality at each dose level was as follows (number dead/number treated in parenthesis): at 0.72 mg/L (1/5 males), at 0.95 mg/L (2/5 males, 1/5 females), at 1.42 mg/L (4/5 males, 2/5 females), and at 3.19 mg/L (3/5 males, 3/5 females). Prominent in-life observations included aggression, crusted eyes/nose, decreased defecation, gasping, piloerection, ptosis and sensitivity to touch, which were no longer evident in surviving animals by day 8. Activity decreases and respiratory gurgle were observed through Day 14. Discolored eye, polyuria and withdrawn testes were observed only in one animal that died on test. Abnormal necropsy findings in animals that died on test pertained to crusted eyes/nose/mouth; discolored and swollen lungs, discolored stomach and contents, and gas in the gastrointestinal tract. The gross necropsy conducted on each animal surviving to termination of the study revealed no observable abnormalities, except discolored lungs in three animals. LC50 (M) is 1.32 mg/L with 95% confidence interval of 0.53 to 3.35 mg/L, and LC50 (F) is 2.24 mg/L with 95% confidence interval of 0.97 to 5.20 mg/L; Toxicity Category III; Study Acceptable. (Mehta, 06/29/15)

Primary Eye Irritation

53139-0015 283720; Acute Eye Irritation; 814; Rabbit; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4853-98; 03/31/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered to 3 male and 6 female (3 unwashed and 3 washed) rabbits by ocular instillation, Dose: 0.1 ml in the right eye. Observations: For unwashed eyes, "positive" effects persisted through Day 21 post-instillation. One animal/sex exhibited pain (squealing) at the time of treatment. Opacity: from 24 hours to day 21 post-instillation 6/6 treated eyes couldn't be scored due to chemosis and/or discharge. Conjunctival redness: on day 21, 2/6 treated eyes showed score 2 redness and 4/6 treated eyes couldn't be scored due to chemosis and/or discharge; in addition, 5/6 animals showed moderate and 1/6 animals showed severe

alopecia around the eye. Chemosis: on day 21 post-instillation, 3/6 treated eyes had score 3, 2/6 treated eyes had score 2, and 1/6 treated eyes had score 4 chemosis. Discharge: on day 21 post-instillation, 5/6 treated eyes showed score 2, and 1/6 treated eyes showed score 3 discharge. Necrosis was evident in 6/6 treated eyes up to 24 hours post-instillation. For washed eyes, "positive" effects persisted through Day 21 post-instillation. Opacity: on day 21 post-instillation, 1/3 treated eyes showed score 4 opacity, with apparent invasion of cornea by blood vessels, and 2/3 treated eyes couldn't be scored due to chemosis and/or discharge. Conjuctival redness: on day 21 post-instillation, 2/3 treated eyes showed score 3, and 1/3 treated eyes showed score 2 redness; moderate alopecia around the eye was noted for one treated eye. Chemosis: at 21 days post-instillation, 1/3 treated eyes showed score 3, and 2/3 treated eyes showed score 2 chemosis. Discharge: at 21 days post-instillation, 3/3 treated eyes showed score 2 discharge. Toxicity Category I; **Study Acceptable**. (Mehta, 06/30/15)

Primary Dermal Irritation

53139-0016 283721; Acute Dermal Irritation Study; 815; Rabbits; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4854-98; 03/31/99; Kuhn, J.O., The skin of 3 males and 3 female New Zealand albino rabbits was exposed to 0.5 ml of AM 3651P (a.i.: 55.2% total quaternary ammonium chloride)/site, one site/animal, for 4 hours under a semi-occlusive wrap. Erythema: at 1 hour post-application, 5/6 animals showed score 2, and 1/6 animals showed score 1 erythema; from 24 hours to day 7 post-application 6/6 treated sites showed score 2 erythema; day 10 post-application, 5/6 sites showed score 2 and 1/6 treated sites showed score 1 erythema; day 14 post-application, 2/6 treated sites showed score 4, 2/6 sites showed score 2, and 2/6 sites showed score 1 erythema. Edema: at 1 hour post-application, 3/6 rabbits showed score 1, 2/6 sites showed score 2, and 1/6 sites showed score 3 edema; at 24 hours post-application, 3/6 sites showed score 1, and 3/6 sites showed score 2 edema; at 48 and at 72 hours post-application, 5/6 sites showed score 1 edema; at day 7 and at day 10 post-application, 3/6 sites showed score 1 edema; at day 14 post-application, 1/6 rabbits showed score 1 edema. **Toxicity Category I** (severe erythema (score 4) persisted up to study termination); Study Acceptable. (Mehta, 06/30/15)

Dermal Sensitization

53139-0017 283722; Skin Sensitization Study; 816; Guinea Pigs; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4855-98; 05/07/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride); 20 Guinea pigs (5 test article induced/sex and 5 naïve control/sex); for each induction treatment, test animals were treated by introducing the test substance beneath a 3.8 x 5 cm patch (a 1.6 x 2.8 cm gauze pad secured to a 3.8 x 5 cm piece of adhesive) known as a Coverlet adhesive dressing. Each adhesive coverlet patch was placed laterally from the midline of the back on the left front quadrant of the exposure area. A strip of clear polyethylene film was placed over the patch and taped in place to secure the patch. Each animal was then placed in a restrainer for approximately six hours. At the end of the exposure period, the animals were removed from the restrainers, the wrappings and patches were removed, and the animals were returned to their cages. Test animals were treated once weekly for three weeks with 0.4 mL of a 75% v/v test substance dilution in deionized water. Induction treatments were on days 1, 8 and 15. The same treatment regimen and test site location was used for all three induction treatments. Control animals remained untreated during the induction phase of the study. After a two-week rest period, all animals were each challenged at a virgin test site with an application of 0.4 mL of

a 50% v/v test substance dilution in deionized water. The challenge treatment was on day 29. The dose was applied in a manner identical to the induction treatments. Approximately 24 and 48 hours after each application readings were made for a sensitization response (erythema). The test substance produced no positive reaction (scores ≥ 1) in either the test animals or the naive control animals after the challenge treatment. Toxicity Category: Not a contact Sensitizer; **Study Acceptable**. (Mehta, 07/01/15)

CONCLUSIONS: Are data adequate to support registration?

The AM 3651P acute oral and inhalation toxicity, primary eye and dermal irritation, and dermal sensitization studies were acceptable. Although acute dermal toxicity study is unacceptable and not upgradable, study supports Toxicity Category II acute dermal toxicity hazard.

RECOMMENDATIONS: What type of registration action is being requested? In case of ongoing registration, register or do not register? What other specific studies or data are requested?

Submitted for a Section 3 Registration.

The data reviewed are adequate for a complete acute toxicological evaluation.

The product label does not adequately identify the Toxicity Category I primary skin irritation hazard and the Toxicity category II acute dermal toxicity hazard indicated by the data reviewed (see note below).*

The First Aid statements are adequate with regard to the assigned acute toxicity categories.

Registration is not recommended at this time.

* Note: adding precautionary language for toxicity category I primary skin irritation hazard precludes the need for acute dermal toxicity category II precautionary language.

Staff Toxicologist **Date**

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
HUMAN HEALTH ASSESSMENT BRANCH
TOXICOLOGY STUDY EVALUATION WORKSHEET

I. STUDY IDENTIFICATION

Active Ingredient: 1. 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; 2. n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{16}) dimethyl benzyl ammonium chloride; 3. octyl decyl dimethyl ammonium chloride; 4. didecyl dimethyl ammonium chloride; 5. dioctyl dimethyl ammonium chloride
Formulated Product Name: AM 3651P
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5. 1710 **ID #:** 269397
Document #: 53139-0017 **Record #:** 283722
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Study Type: 816-Skin Sensitization Study
Full Study Title: DERMAL SENSITIZATION STUDY IN GUINEA PIGS
Company Sponsor: BioShield Technologies, Inc., Norcross, GA
Conducting Laboratory: Stillmeadow, Inc., Sugar Land, TX
Final Report Date: 05/07/99
Study Interval: 01/13/99-2/12/99

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? -No
Is study acceptable? -Yes

- **Meets EPA guidelines**
- Yes - **Minor variances from guidelines**
- **Major variances from guidelines**
- **Could be upgraded with additional information (see VI-A)**

Yes - **Has useful data**
- **Insufficient data**
- **Non EPA validated study**
- **Other**_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?: No

C. ONE LINER-One or two sentence summary of the study:
53139-0017 283722; Skin Sensitization Study; 816; Guinea Pigs; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4855-98; 05/07/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride); 20 Guinea pigs (5 test article induced/sex and 5 naïve control/sex); for each induction treatment, test animals were treated by introducing the test substance beneath a 3.8 x 5 cm patch (a 1.6 x 2.8 cm gauze pad secured to a 3.8 x 5 cm piece of adhesive) known as a Coverlet adhesive dressing. Each adhesive coverlet patch was placed laterally from the midline of the back on the left front quadrant of the exposure area. A strip of clear polyethylene film was placed over the patch and taped in place to secure the patch. Each animal was then placed in a restrainer for approximately six hours. At the end of the exposure period, the animals were removed from the restrainers, the wrappings and patches were removed, and the animals were returned to their cages. Test animals were treated once weekly for three weeks with 0.4 mL of a 75% v/v test substance dilution in deionized water. Induction treatments were on days 1, 8 and

15. The same treatment regimen and test site location was used for all three induction treatments. Control animals remained untreated during the induction phase of the study. After a two-week rest period, all animals were each challenged at a virgin test site with an application of 0.4 mL of a 50% v/v test substance dilution in deionized water. The challenge treatment was on day 29. The dose was applied in a manner identical to the induction treatments. Approximately 24 and 48 hours after each application readings were made for a sensitization response (erythema). The test substance produced no positive reaction (scores ≥ 1) in either the test animals or the naive control animals after the challenge treatment. Toxicity Category: Not a contact Sensitizer; **Study Acceptable**. (Mehta, 07/01/15)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?: Yes

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Staff Toxicologist **Date**

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Guinea Pigs
Strain: Hartley albino
Source of animals: Charles River; Hdq: Wilmington, MA
Age at start: Not provided; Sex: males and females. Weight: males weighing: 509-557 grams and females weighing 444-552 grams.
Route of administration: Dermal application
Vehicle: none
Period of treatment: Induction phase: three applications at 6 hours per exposure (7 days between each exposure); Challenge phase: 6-hr exposure and examined 1 and 2 days after removal of dressing.

B. BACKGROUND (including relationship of this study to other studies): A group of 4 guinea pigs (2/sex) were used to determine the highest non-irritating concentration (HNIC) of the test substance prior to the challenge dose. Concentrations tested in the screening were 100% (undiluted), and 75%, 50% and 25% v/v dilutions in deionized water, with each animal receiving 0.4 ml of each concentration at different sites. The HNIC selected for challenge phase was 50 % based on three scores of 0 and one score of 0.5. The concentration chosen for induction was 75% based on four scores of 0.5.

C. TREATMENT LEVELS AND GROUP SIZE:

Groups	Induction Phase	Challenge Phase	# of Males	# of Females
Test Group	75% v/v test substance dilution in deionized water	50% v/v test substance dilution in deionized water	5	5
Naïve Control Group	Untreated	50% v/v test substance dilution in deionized water	5	5

IV. STUDY DESIGN AND EVALUATION

A. STUDY PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** AM 3651P; Composition: 55.2% total quaternary ammonium chloride; Batch#: B129828B-2 and B129828B-3. Physical properties: pale yellow liquid, date of received: 01/04/99 and 01/06/99, stored at room temperature. pH: 6.96. Expiration: 12/29/99.

*2. **Analysis of dosing material:** Purity of test substance was provided as 55.2% total quaternary ammonium chloride. Records pertaining to identity, synthesis methods and location of documentation are the responsibility of the sponsor. A certificate of analysis specifying purity of test substance was not provided. Stability details were not provided. These are considered minor deficiencies and had no impact on study outcome.

3. **Animal selection:** OK

4. **Animal husbandry:** Animal room temperature and relative humidity ranges were maintained at 20±3°C and 30-70%, respectively.

5. **Mortality:** NA

*6. **Number of animals:** fewer animals than recommended by the guidelines were used in this study. EPA guidelines recommend a minimum of 20 animals in test group and 10 animals in control group. This is considered a minor deficiency and will not have an impact on study outcome.

7. **Randomization of animals:** OK

8. **Dose level selection:** OK

9. **Route of administration:** OK

10. **Exposure conditions:** OK; for each induction treatment, test animals were treated by introducing the test substance beneath a 3.8 x 5 cm patch (a 1.6 x 2.8 cm gauze pad secured to a 3.8 x 5 cm piece of adhesive) known as a Coverlet adhesive dressing. Each adhesive coverlet patch was placed laterally from the midline of the back on the left front quadrant of the exposure area. A strip of clear polyethylene film was placed over the patch and taped in place to secure the patch. Each animal was then placed in a restrainer for approximately six hours. At the end of the exposure period, the animals were removed from the restrainers, the wrappings and patches were removed, and the animals were returned to their cages. Test animals were treated once weekly for three weeks with 0.4 mL of a 75% v/v dilution in deionized water. Induction treatments were on days 1, 8 and 15. The same treatment regimen and test site location was used for all three induction treatments. Control animals remained untreated during the induction phase of the study. After a two-week rest period, all animals were each challenged at a virgin test site with an application of 0.4 mL of a 50% v/v dilution in deionized water. The challenge treatment was on day 29. The dose was applied in a manner identical to the induction treatments. Approximately 24 and 48 hours after each application readings were made for a sensitization response (erythema).

11. **Controls:** OK; although a concurrent positive control was not included in the study, historical control data from study# 4716-98 (12/23/98) were included with the report. This study was conducted as per Buehler sensitization method, and demonstrated the sensitivity of the guinea pigs to the positive control material (1-chloro-2,4-

dinitrobenzene). For test group, positive scores (scores ≥ 1) were noted in 9 of 10 guinea pigs at 24 and at 48 hours after challenge, indicating that the test system used was capable of detecting a known sensitizer. For naïve control group, positive scores (scores ≥ 1) were noted in 2 of 10 guinea pigs at 24 hours and for 5/10 guinea pigs at 48 hours after challenge. Note: at 48 hours post-challenge, 50% naïve control animals showed positive score. This is considered a minor deficiency and will not have an impact on study outcome.

12. **Observations:** Dermal irritation scores were recorded at 1, 2 days after removal of the dressings (induction and challenge phases).
13. **Necropsies:** NA
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** GLP compliance statement and quality assurance audit record included in the report.
19. **Other:** NA

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. **EFFECTS REPORTED:** The test substance produced no positive reaction (scores ≥ 1) in either the test animals or the naive control animals after the challenge treatment.

B. ACUTE TOXICITY VALUE (LD50, LC50, etc.): NA

C. TOXICITY CATEGORY: Not a contact sensitizer.

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). What are they and can they be corrected with additional information? None **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? No **Are there any recommendations specific to this study?:** None

TO: Teresa Coe, Environmental Scientist
Pesticide Registration Branch

FROM: Human Health Assessment Branch **Date:** 07/02/15

PRODUCT REGISTRATION RECOMMENDATION SHEET

Formulated Product Name: XMICROBE DP
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5.1710 **ID #:** 269397
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Document #: 53139-0012 thru -0017
Company Name: Xmicrobe, LLC., Clackamas, OR

RECOMMENDATION:

Submitted for a Section 3 Registration.

The data reviewed are adequate for a complete acute toxicological evaluation.

The product label does not adequately identify the Toxicity Category I primary skin irritation hazard and the Toxicity category II acute dermal toxicity hazard indicated by the data reviewed (see note below).*

The First Aid statements are adequate with regard to the assigned acute toxicity categories.

Registration is not recommended at this time.

* Note: adding precautionary language for toxicity category I primary skin irritation hazard precludes the need for acute dermal toxicity category II precautionary language.

Staff Toxicologist **Date**

TO--File: Registration **Environmental Scientist:** Teresa Coe
Branch: Registration

FROM—Human Health Assessment

DATA PACKAGE SUMMARY AND RECOMMENDATION SHEET

Active Ingredient: 1. 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; 2. n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{18}) dimethyl benzyl ammonium chloride; 3. octyl decyl dimethyl ammonium chloride; 4. didecyl dimethyl ammonium chloride; 5. dioctyl dimethyl ammonium chloride
Formulated Product Name: Xmicrobe DP
Formulation: active ingredient: 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride 35.60%; n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{18}) dimethyl benzyl ammonium chloride 6.40%; octyl decyl dimethyl ammonium chloride 4.80%; didecyl dimethyl ammonium chloride 2.88%; dioctyl dimethyl ammonium chloride 1.92%; inert ingredients: 48.40%*
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5.1710 **ID #:** 269397
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Document #: 53139-0012 thru -0017
Company Name: Xmicrobe, LLC., Clackamas, OR
* Contains over 6% methanol

SUMMARY ("One-liners" from each study worksheet, significant information not mentioned in worksheets, other pertinent information for ongoing review of registration. Attach additional sheets if needed):

The Environmental Scientist cited data contained in data volumes 53139-0012 thru -0017 to support registration of the subject product.

The differences in formulation between the test article and the subject product are of minimal toxicological concern. The acute toxicity studies are suitable for bridging to the subject product.

AM 3651P (a.i.: 55.2% total quaternary ammonium chloride)
- Acute Toxicity Categories

Acute Oral Toxicity (LD_{50})	III
Acute Dermal Toxicity (LD_{50})	Study Unacceptable*
Acute Inhalation Toxicity (LC_{50})	III
Primary Eye Irritation	I
Primary Dermal Irritation	I
Dermal Sensitization	Negative for dermal sensitization

*See Conclusions

AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) - Acute Toxicity Studies

Acute Oral Toxicity (LD_{50})

53139-0012 283717; Acute oral toxicity; 811; Rat; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4850-98; 04/21/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered in a single dose by oral gavage to 15 males and 25 females. The rats were dosed in the following order and at the following dose levels (number dead/number treated in parentheses); at 5050 (5/5 F, 5/5 M), at 2000 (1/5 F, 3/5 M), at 3000 (3/5 F); at 1000 (2/5F, 0/5 M), and at 500 (0/5 F) mg/kg. Clinical observations: At 500 mg/kg dose level (5 females), all females survived exposure to the test substance; Body weight gain was unaffected by the administration of the test substance; All animals appeared normal for the duration of the study; The gross necropsy at the conclusion of the study revealed no observable abnormalities. At 1000, 2000, 3000 and 5050 mg/kg dose levels mortality was as follows: at 1000 mg/kg dose level (5/sex), 2 females died within 3 days of test substance administration; at 2000 mg/kg dose level (5/sex), three males and 1 female died within 5 days of test substance administration; at 3000 mg/kg dose level (5 females), 3 females died within 6 days of test substance administration; at 5050 mg/kg dose level (5/sex), all animals died within 6 days of test substance administration. Prominent in-life observations for 1000, 2000, 3000 and 5050 mg/kg dose levels included alopecia (through day 14), activity decrease, anus red and swollen, crusted muzzle and eyes, diarrhea and soft feces, decreased defecation, respiratory chirp gurgle, piloerection, ptosis, polyuria, salivation, swollen face, sensitivity to touch, stained fur, withdrawn testes and walking on tiptoe, which were no longer evident in surviving animals by Day 13. Ataxia, nasal and ocular discharge, distended abdomen and gasping were observed only in animals that died on test. Body weight gain in surviving animals was largely unaffected by the administration of the test substance. One of seven males and three of nine females lost or failed to gain weight between days 0 and 7. The gross necropsy on animals that died on test revealed matted and stained fur; discolored lungs, spleen and liver; thickened stomach mucosa; gas and discolored contents in the gastrointestinal tract. The gross necropsy in animals surviving to termination of the study revealed no observable abnormalities, except alopecia in the genital area of three animals. LD50 (M/F) is > 500 mg/kg but < 2000 mg/kg; Toxicity Category III; **Study Acceptable**. (Mehta, 06/24/15)

Acute Dermal Toxicity (LD_{50})

53139-0013 283718; Acute dermal toxicity; 812; Rabbit; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4851-98; 04/21/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered to 5 males and 20 female rabbits. The rabbits were dosed at 5050 (5/sex), 5500 (5 F), 3500 (5 F), and 500 (5 F) mg/kg dose levels, 24-hour exposure, occlusive wrap. Clinical observations: At 500 mg/kg dose level (5 females), all females survived exposure to the test substance; Body weight gain was unaffected by the administration of the test substance; All animals appeared normal for the duration of the study; The gross necropsy at the conclusion of the study revealed no observable abnormalities. At 3500 (5 females) and at 5050 (5/sex) mg/kg dose level, two female deaths were noted at each dose level. At 5500 mg/kg dose level (5 females), no mortality was noted. Prominent in-life observations for 3500, 5050 and 5500 mg/kg dose levels included diarrhea and soft feces, decreased and no defecation, and not

eating. Surviving animals were asymptomatic by Day 4, except for one animal with decreased defecation on Day 12. Dermal irritation in animals at all dose levels included very slight to severe erythema, very slight to moderate edema, atonia, coriaceousness, desquamation, eschar and/or necrosis. Body weight gain in several surviving animals was affected by the administration of the test substance. Four of five males and six of eleven females lost or failed to gain weight between Days 0 and 7. Gross necropsy in animals that died on test revealed ocular and nasal discharge, hemorrhage around eye, discolored abdominal skin, lungs discolored and having lesions, stomach wall and liver friable; fluid in the abdomen and gas in the intestines. Gross necropsy in animals surviving to termination of the study revealed no observable abnormalities. There were two female deaths each at 3500 and 5050 mg/kg dose levels, and no deaths at 5500 mg/kg dose level. Hence, a dose response relationship for females was not established; Study Unacceptable, Not Upgradable. (Mehta, 06/26/15)

Acute Inhalation Toxicity (LC_{50})

53139-0014 283719; Acute inhalation toxicity; 813; Rat; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4852-98; 04/26/99; Bennick, J. E., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered to 5 animals/sex at 3.19 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 2.7 μm (3.15); 5 animals/sex at 1.42 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 2.3 μm (7.3); 5 animals/sex at 0.95 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 3.6 μm (4.25); 5 males at 0.72 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 1.5 μm (3.6), 4-hour nose-only exposure. Clinical observation: Mortality at each dose level was as follows (number dead/number treated in parenthesis): at 0.72 mg/L (1/5 males), at 0.95 mg/L (2/5 males, 1/5 females), at 1.42 mg/L (4/5 males, 2/5 females), and at 3.19 mg/L (3/5 males, 3/5 females). Prominent in-life observations included aggression, crusted eyes/nose, decreased defecation, gasping, piloerection, ptosis and sensitivity to touch, which were no longer evident in surviving animals by day 8. Activity decreases and respiratory gurgle were observed through Day 14. Discolored eye, polyuria and withdrawn testes were observed only in one animal that died on test. Abnormal necropsy findings in animals that died on test pertained to crusted eyes/nose/mouth; discolored and swollen lungs, discolored stomach and contents, and gas in the gastrointestinal tract. The gross necropsy conducted on each animal surviving to termination of the study revealed no observable abnormalities, except discolored lungs in three animals. LC50 (M) is 1.32 mg/L with 95% confidence interval of 0.53 to 3.35 mg/L, and LC50 (F) is 2.24 mg/L with 95% confidence interval of 0.97 to 5.20 mg/L; Toxicity Category III; Study Acceptable. (Mehta, 06/29/15)

Primary Eye Irritation

53139-0015 283720; Acute Eye Irritation; 814; Rabbit; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4853-98; 03/31/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered to 3 male and 6 female (3 unwashed and 3 washed) rabbits by ocular instillation, Dose: 0.1 ml in the right eye. Observations: For unwashed eyes, "positive" effects persisted through Day 21 post-instillation. One animal/sex exhibited pain (squealing) at the time of treatment. Opacity: from 24 hours to day 21 post-instillation 6/6 treated eyes couldn't be scored due to chemosis and/or discharge. Conjunctival redness: on day 21, 2/6 treated eyes showed score 2 redness and 4/6 treated eyes couldn't be scored due to chemosis and/or discharge; in addition, 5/6 animals showed moderate and 1/6 animals showed severe

a 50% v/v test substance dilution in deionized water. The challenge treatment was on day 29. The dose was applied in a manner identical to the induction treatments. Approximately 24 and 48 hours after each application readings were made for a sensitization response (erythema). The test substance produced no positive reaction (scores ≥ 1) in either the test animals or the naive control animals after the challenge treatment. Toxicity Category: Not a contact Sensitizer; **Study Acceptable**. (Mehta, 07/01/15)

CONCLUSIONS: Are data adequate to support registration?

The AM 3651P acute oral and inhalation toxicity, primary eye and dermal irritation, and dermal sensitization studies were acceptable. Although acute dermal toxicity study is unacceptable and not upgradable, study supports Toxicity Category II acute dermal toxicity hazard.

RECOMMENDATIONS: What type of registration action is being requested? In case of ongoing registration, register or do not register? What other specific studies or data are requested?

Submitted for a Section 3 Registration.

The data reviewed are adequate for a complete acute toxicological evaluation.

The product label does not adequately identify the Toxicity Category I primary skin irritation hazard and the Toxicity category II acute dermal toxicity hazard indicated by the data reviewed (see note below).*

The First Aid statements are adequate with regard to the assigned acute toxicity categories.

Registration is not recommended at this time.

* Note: adding precautionary language for toxicity category I primary skin irritation hazard precludes the need for acute dermal toxicity category II precautionary language.

Staff Toxicologist **Date**

KRK Consulting LLC

5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
E-mail: kevinkutcel@gmail.com

October 28, 2015

US EPA (NOTIF)
Office of Pesticide Programs
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Notification per California Department of Pesticide Regulation (EPA No. 87583-5)

In their review of the label, the California Department of Pesticide Regulation has requested that PureShield Inc. file a notification with the US EPA with the following changes to the label:

- Removal of all fungicidal/fungistatic and algicidal/algistatic claims on the label. See removal of heading on page 3.
- Addition of Non-Refillable container language for Container Handling in the Storage and Disposal Section.

Please accept the attached one copy of the revised label for Reg. No. 87583-5 showing the highlighted changes and three (3) copies of the revised label.

Attached is EPA Form 8570-1 regarding this notification as required in PR Notice 1998-10. This notification is consistent with the guidance in PR Notice 1998-10 and the requirements of EPA's regulations at 40 CFR 156.46, 156.140, 156.144, 156,146 and 156.156 and no other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand this it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of PR Notice 98-10 and CFR 156.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Please note that KRK Consulting LLC is the authorized agent handling all correspondence for PureShield Inc. and therefore all responses should be directed to the contact information on the letterhead above.

Best Regards,

Kevin R. Kutcel,
Agent for PureShield Inc.

Please read instructions on reverse before *pleting form.* Form Approved. OMB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
PureShield, Inc. / 87583-5		[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
PureShield, Inc. / Bio-Protect DP	31	

5. Name and Address of Applicant *(Include ZIP Code)*

PureShield Inc.
1445 Jupiter Park, Suite 11
Jupiter, FL 33458

[x] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [x] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Please see cover letter.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container		[x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [x] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

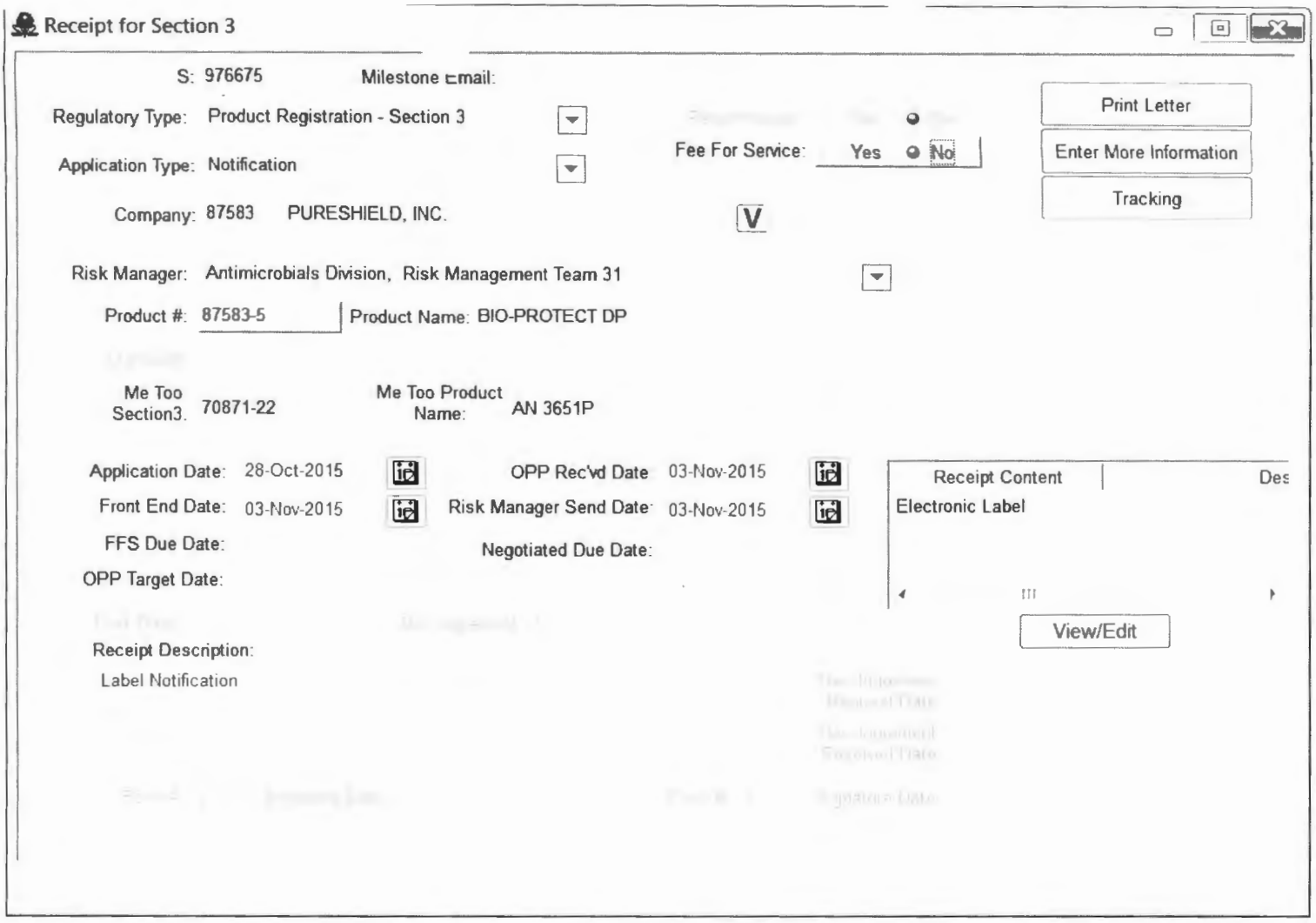
Name	Title	Telephone No. (Include Area Code)
Kevin Kutcel	Agent	440-263-7305

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
	Agent
4. Typed Name	**5. Date**
Kevin R. Kutcel	Oct 28, 2015


Receipt for Section 3
S: 976675
Milestone Email:
Regulatory Type: Product Registration - Section 3
Application Type: Notification
Company: 87583 PURESHIELD, INC.
Fee For Service: Yes No
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 31
Product #: 87583-5
Product Name: BIO-PROTECT DP
Me Too Section3. 70871-22
Me Too Product Name: AN 3651P
Application Date: 28-Oct-2015
Front End Date: 03-Nov-2015
FFS Due Date:
OPP Target Date:
OPP Rec'vd Date 03-Nov-2015
Risk Manager Send Date: 03-Nov-2015
Negotiated Due Date:
Receipt Content
Des
Electronic Label
View/Edit
Receipt Description:
Label Notification

L

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
HUMAN HEALTH ASSESSMENT BRANCH
TOXICOLOGY STUDY EVALUATION WORKSHEET

I. STUDY IDENTIFICATION

Active Ingredient: 1. 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; 2. n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{16}) dimethyl benzyl ammonium chloride; 3. octyl decyl dimethyl ammonium chloride; 4. didecyl dimethyl ammonium chloride; 5. dioctyl dimethyl ammonium chloride
Formulated Product Name: AM 3651P
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5. 1710 **ID #:** 269397
Document #: 53139-0017 **Record #:** 283722
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Study Type: 816-Skin Sensitization Study
Full Study Title: DERMAL SENSITIZATION STUDY IN GUINEA PIGS
Company Sponsor: BioShield Technologies, Inc., Norcross, GA
Conducting Laboratory: Stillmeadow, Inc., Sugar Land, TX
Final Report Date: 05/07/99
Study Interval: 01/13/99-2/12/99

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? -No
Is study acceptable? -Yes

- **Meets EPA guidelines**
- Yes - **Minor variances from guidelines**
- **Major variances from guidelines**
- **Could be upgraded with additional information (see VI-A)**

Yes - **Has useful data**
- **Insufficient data**
- **Non EPA validated study**
- **Other**_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?: No

C. ONE LINER-One or two sentence summary of the study:
53139-0017 283722; Skin Sensitization Study; 816; Guinea Pigs; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4855-98; 05/07/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride); 20 Guinea pigs (5 test article induced/sex and 5 naïve control/sex); for each induction treatment, test animals were treated by introducing the test substance beneath a 3.8 x 5 cm patch (a 1.6 x 2.8 cm gauze pad secured to a 3.8 x 5 cm piece of adhesive) known as a Coverlet adhesive dressing. Each adhesive coverlet patch was placed laterally from the midline of the back on the left front quadrant of the exposure area. A strip of clear polyethylene film was placed over the patch and taped in place to secure the patch. Each animal was then placed in a restrainer for approximately six hours. At the end of the exposure period, the animals were removed from the restrainers, the wrappings and patches were removed, and the animals were returned to their cages. Test animals were treated once weekly for three weeks with 0.4 mL of a 75% v/v test substance dilution in deionized water. Induction treatments were on days 1, 8 and

15. The same treatment regimen and test site location was used for all three induction treatments. Control animals remained untreated during the induction phase of the study. After a two-week rest period, all animals were each challenged at a virgin test site with an application of 0.4 mL of a 50% v/v test substance dilution in deionized water. The challenge treatment was on day 29. The dose was applied in a manner identical to the induction treatments. Approximately 24 and 48 hours after each application readings were made for a sensitization response (erythema). The test substance produced no positive reaction (scores ≥ 1) in either the test animals or the naive control animals after the challenge treatment. Toxicity Category: Not a contact Sensitizer; **Study Acceptable**. (Mehta, 07/01/15)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?: Yes

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Staff Toxicologist **Date**

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Guinea Pigs
Strain: Hartley albino
Source of animals: Charles River; Hdq: Wilmington, MA
Age at start: Not provided; Sex: males and females. Weight: males weighing: 509-557 grams and females weighing 444-552 grams.
Route of administration: Dermal application
Vehicle: none
Period of treatment: Induction phase: three applications at 6 hours per exposure (7 days between each exposure); Challenge phase: 6-hr exposure and examined 1 and 2 days after removal of dressing.

B. BACKGROUND (including relationship of this study to other studies): A group of 4 guinea pigs (2/sex) were used to determine the highest non-irritating concentration (HNIC) of the test substance prior to the challenge dose. Concentrations tested in the screening were 100% (undiluted), and 75%, 50% and 25% v/v dilutions in deionized water, with each animal receiving 0.4 ml of each concentration at different sites. The HNIC selected for challenge phase was 50 % based on three scores of 0 and one score of 0.5. The concentration chosen for induction was 75% based on four scores of 0.5.

C. TREATMENT LEVELS AND GROUP SIZE:

Groups	Induction Phase	Challenge Phase	# of Males	# of Females
Test Group	75% v/v test substance dilution in deionized water	50% v/v test substance dilution in deionized water	5	5
Naïve Control Group	Untreated	50% v/v test substance dilution in deionized water	5	5

IV. STUDY DESIGN AND EVALUATION

A. STUDY PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** AM 3651P; Composition: 55.2% total quaternary ammonium chloride; Batch#: B129828B-2 and B129828B-3. Physical properties: pale yellow liquid, date of received: 01/04/99 and 01/06/99, stored at room temperature. pH: 6.96. Expiration: 12/29/99.

*2. **Analysis of dosing material:** Purity of test substance was provided as 55.2% total quaternary ammonium chloride. Records pertaining to identity, synthesis methods and location of documentation are the responsibility of the sponsor. A certificate of analysis specifying purity of test substance was not provided. Stability details were not provided. These are considered minor deficiencies and had no impact on study outcome.

3. **Animal selection:** OK

4. **Animal husbandry:** Animal room temperature and relative humidity ranges were maintained at 20±3°C and 30-70%, respectively.

5. **Mortality:** NA

*6. **Number of animals:** fewer animals than recommended by the guidelines were used in this study. EPA guidelines recommend a minimum of 20 animals in test group and 10 animals in control group. This is considered a minor deficiency and will not have an impact on study outcome.

7. **Randomization of animals:** OK

8. **Dose level selection:** OK

9. **Route of administration:** OK

10. **Exposure conditions:** OK; for each induction treatment, test animals were treated by introducing the test substance beneath a 3.8 x 5 cm patch (a 1.6 x 2.8 cm gauze pad secured to a 3.8 x 5 cm piece of adhesive) known as a Coverlet adhesive dressing. Each adhesive coverlet patch was placed laterally from the midline of the back on the left front quadrant of the exposure area. A strip of clear polyethylene film was placed over the patch and taped in place to secure the patch. Each animal was then placed in a restrainer for approximately six hours. At the end of the exposure period, the animals were removed from the restrainers, the wrappings and patches were removed, and the animals were returned to their cages. Test animals were treated once weekly for three weeks with 0.4 mL of a 75% v/v dilution in deionized water. Induction treatments were on days 1, 8 and 15. The same treatment regimen and test site location was used for all three induction treatments. Control animals remained untreated during the induction phase of the study. After a two-week rest period, all animals were each challenged at a virgin test site with an application of 0.4 mL of a 50% v/v dilution in deionized water. The challenge treatment was on day 29. The dose was applied in a manner identical to the induction treatments. Approximately 24 and 48 hours after each application readings were made for a sensitization response (erythema).

11. **Controls:** OK; although a concurrent positive control was not included in the study, historical control data from study# 4716-98 (12/23/98) were included with the report. This study was conducted as per Buehler sensitization method, and demonstrated the sensitivity of the guinea pigs to the positive control material (1-chloro-2,4-

dinitrobenzene). For test group, positive scores (scores ≥ 1) were noted in 9 of 10 guinea pigs at 24 and at 48 hours after challenge, indicating that the test system used was capable of detecting a known sensitizer. For naïve control group, positive scores (scores ≥ 1) were noted in 2 of 10 guinea pigs at 24 hours and for 5/10 guinea pigs at 48 hours after challenge. Note: at 48 hours post-challenge, 50% naïve control animals showed positive score. This is considered a minor deficiency and will not have an impact on study outcome.

12. **Observations:** Dermal irritation scores were recorded at 1, 2 days after removal of the dressings (induction and challenge phases).
13. **Necropsies:** NA
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** GLP compliance statement and quality assurance audit record included in the report.
19. **Other:** NA

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. **EFFECTS REPORTED:** The test substance produced no positive reaction (scores ≥ 1) in either the test animals or the naive control animals after the challenge treatment.

B. ACUTE TOXICITY VALUE (LD50, LC50, etc.): NA

C. TOXICITY CATEGORY: Not a contact sensitizer.

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). What are they and can they be corrected with additional information? None **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? No **Are there any recommendations specific to this study?:** None

alopecia around the eye. Chemosis: on day 21 post-instillation, 3/6 treated eyes had score 3, 2/6 treated eyes had score 2, and 1/6 treated eyes had score 4 chemosis. Discharge: on day 21 post-instillation, 5/6 treated eyes showed score 2, and 1/6 treated eyes showed score 3 discharge. Necrosis was evident in 6/6 treated eyes up to 24 hours post-instillation. For washed eyes, "positive" effects persisted through Day 21 post-instillation. Opacity: on day 21 post-instillation, 1/3 treated eyes showed score 4 opacity, with apparent invasion of cornea by blood vessels, and 2/3 treated eyes couldn't be scored due to chemosis and/or discharge. Conjuctival redness: on day 21 post-instillation, 2/3 treated eyes showed score 3, and 1/3 treated eyes showed score 2 redness; moderate alopecia around the eye was noted for one treated eye. Chemosis: at 21 days post-instillation, 1/3 treated eyes showed score 3, and 2/3 treated eyes showed score 2 chemosis. Discharge: at 21 days post-instillation, 3/3 treated eyes showed score 2 discharge. Toxicity Category I; **Study Acceptable**. (Mehta, 06/30/15)

Primary Dermal Irritation

53139-0016 283721; Acute Dermal Irritation Study; 815; Rabbits; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4854-98; 03/31/99; Kuhn, J.O., The skin of 3 males and 3 female New Zealand albino rabbits was exposed to 0.5 ml of AM 3651P (a.i.: 55.2% total quaternary ammonium chloride)/site, one site/animal, for 4 hours under a semi-occlusive wrap. Erythema: at 1 hour post-application, 5/6 animals showed score 2, and 1/6 animals showed score 1 erythema; from 24 hours to day 7 post-application 6/6 treated sites showed score 2 erythema; day 10 post-application, 5/6 sites showed score 2 and 1/6 treated sites showed score 1 erythema; day 14 post-application, 2/6 treated sites showed score 4, 2/6 sites showed score 2, and 2/6 sites showed score 1 erythema. Edema: at 1 hour post-application, 3/6 rabbits showed score 1, 2/6 sites showed score 2, and 1/6 sites showed score 3 edema; at 24 hours post-application, 3/6 sites showed score 1, and 3/6 sites showed score 2 edema; at 48 and at 72 hours post-application, 5/6 sites showed score 1 edema; at day 7 and at day 10 post-application, 3/6 sites showed score 1 edema; at day 14 post-application, 1/6 rabbits showed score 1 edema. **Toxicity Category I** (severe erythema (score 4) persisted up to study termination); Study Acceptable. (Mehta, 06/30/15)

Dermal Sensitization

53139-0017 283722; Skin Sensitization Study; 816; Guinea Pigs; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4855-98; 05/07/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride); 20 Guinea pigs (5 test article induced/sex and 5 naïve control/sex); for each induction treatment, test animals were treated by introducing the test substance beneath a 3.8 x 5 cm patch (a 1.6 x 2.8 cm gauze pad secured to a 3.8 x 5 cm piece of adhesive) known as a Coverlet adhesive dressing. Each adhesive coverlet patch was placed laterally from the midline of the back on the left front quadrant of the exposure area. A strip of clear polyethylene film was placed over the patch and taped in place to secure the patch. Each animal was then placed in a restrainer for approximately six hours. At the end of the exposure period, the animals were removed from the restrainers, the wrappings and patches were removed, and the animals were returned to their cages. Test animals were treated once weekly for three weeks with 0.4 mL of a 75% v/v test substance dilution in deionized water. Induction treatments were on days 1, 8 and 15. The same treatment regimen and test site location was used for all three induction treatments. Control animals remained untreated during the induction phase of the study. After a two-week rest period, all animals were each challenged at a virgin test site with an application of 0.4 mL of

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
HUMAN HEALTH ASSESSMENT BRANCH
TOXICOLOGY STUDY EVALUATION WORKSHEET

I. STUDY IDENTIFICATION

Active Ingredient: 1. 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; 2. n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{16}) dimethyl benzyl ammonium chloride; 3. octyl decyl dimethyl ammonium chloride; 4. didecyl dimethyl ammonium chloride; 5. dioctyl dimethyl ammonium chloride
Formulated Product Name: AM 3651P
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5. 1710 **ID #:** 269397
Document #: 53139-0012 **Record #:** 283717
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Study Type: 811-Acute Oral Toxicity
Full Study Title: ACUTE ORAL TOXICITY STUDY IN RATS
Company Sponsor: BioShield Technologies, Inc., Norcross, GA
Conducting Laboratory: Stillmeadow, Inc., Sugar Land, TX
Final Report Date: 04/21/99
Study Interval: 1/13/99-3/10/99

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? -No
Is study acceptable? -Yes

- **Meets EPA guidelines**
- Yes - **Minor variances from guidelines**
- **Major variances from guidelines**
- **Could be upgraded with additional information (see VI-A)**

Yes - **Has useful data**
- **Insufficient data**
- **Non EPA validated study**
- **Other**_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?: no

C. ONE LINER-One or two sentence summary of the study:
53139-0012 283717; Acute oral toxicity; 811; Rat; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4850-98; 04/21/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered in a single dose by oral gavage to 15 males and 25 females. The rats were dosed in the following order and at the following dose levels (number dead/number treated in parentheses); at 5050 (5/5 F, 5/5 M), at 2000 (1/5 F, 3/5 M), at 3000 (3/5 F); at 1000 (2/5F, 0/5 M), and at 500 (0/5 F) mg/kg. Clinical observations: At 500 mg/kg dose level (5 females), all females survived exposure to the test substance; Body weight gain was unaffected by the administration of the test substance; All animals appeared normal for the duration of the study; The gross necropsy at the conclusion of the study revealed no observable abnormalities. At 1000, 2000, 3000 and 5050 mg/kg dose levels mortality was as follows: at 1000 mg/kg dose level (5/sex), 2 females died within 3 days of test substance administration; at 2000 mg/kg dose level (5/sex), three males and 1 female died within 5 days of test substance

administration; at 3000 mg/kg dose level (5 females), 3 females died within 6 days of test substance administration; at 5050 mg/kg dose level (5/sex), all animals died within 6 days of test substance administration. Prominent in-life observations for 1000, 2000, 3000 and 5050 mg/kg dose levels included alopecia (through day 14), activity decrease, anus red and swollen, crusted muzzle and eyes, diarrhea and soft feces, decreased defecation, respiratory chirp gurgle, piloerection, ptosis, polyuria, salivation, swollen face, sensitivity to touch, stained fur, withdrawn testes and walking on tiptoe, which were no longer evident in surviving animals by Day 13. Ataxia, nasal and ocular discharge, distended abdomen and gasping were observed only in animals that died on test. Body weight gain in surviving animals was largely unaffected by the administration of the test substance. One of seven males and three of nine females lost or failed to gain weight between days 0 and 7. The gross necropsy on animals that died on test revealed matted and stained fur; discolored lungs, spleen and liver; thickened stomach mucosa; gas and discolored contents in the gastrointestinal tract. The gross necropsy in animals surviving to termination of the study revealed no observable abnormalities, except alopecia in the genital area of three animals. LD50 (M/F) is > 500 mg/kg but < 2000 mg/kg; Toxicity Category III; **Study Acceptable**. (Mehta, 06/24/15)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?: Yes

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Staff Toxicologist **Date**

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Albino Rat
Strain: HSD: SD
Source of animals: Harlan Sprague Dawley, Inc., Indianapolis, IN
***Age at start:** Approximately 8 to 10 week old males and females; fasting weight of males 222-310 grams and of females 155-227 grams. Females were nulliparous and non-pregnant. Year of birth was mistyped as 1999 instead of 1998.
Route of administration: Oral, by gavage
Vehicle: none
Period of treatment: Single dose, 14-day observation period

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

Dosing Sequence	Dose Level (mg/kg)	Number of animals		Mortality (number dead/number treated)	
		Females	Males	Females	Males
1	5050	5	5	5/5	5/5
2	2000	5	5	1/5	3/5
3	3000	5	-	3/5	-
4	1000	5	5	2/5	0/5
5	500	5	-	0/5	-

IV. STUDY DESIGN AND EVALUATION

A. STUDY PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** AM 3651P; Composition: 55.2% total quaternary ammonium chloride; Batch#: B129828B-2 and B129828B-3. Physical properties: pale yellow liquid, date of received: 01/04/99 and 01/06/99, stored at room temperature. Expiration: 12/29/99.
*2. **Analysis of dosing material:** The test article was administered as received. Purity of test substance was provided as 55.2% total quaternary ammonium chloride. Records pertaining to identity, synthesis methods and location of documentation are the responsibility of the sponsor. A certificate of analysis specifying purity of test substance was not provided. Stability details were not provided. These are considered minor deficiencies and had no impact on study outcome.
3. **Animal selection:** OK
4. **Animal husbandry:** Animal room temperature and relative humidity ranges were maintained at 22±3°C and 30-70%, respectively.
5. **Mortality:** OK
6. **Number of animals:** OK
7. **Randomization of animals:** OK
8. **Dose level selection:** OK
9. **Route of administration:** the test material was administered by gastric intubation using a syringe and ball-tipped dosing needle.
10. **Exposure conditions:** OK
11. **Controls:** NA
12. **Observations:** Observations for mortality and clinical/behavioral signs of toxicity were made at least three times on the day of dosing (Day 0) and at least once daily thereafter for 14 days. Individual body weights were recorded just prior to dosing and on days 7 and 14, or at the time of discovery after death.
13. **Necropsies:** OK
14. **Appropriateness of methods:** OK; OECD test guidelines were followed in the current study, as recommended in US EPA OPPTS 870.1100 guidelines for acute oral toxicity testing.
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** GLP compliance statement and quality assurance audit record included in the report.
19. **Other:** NA

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED: At 500 mg/kg dose level (5 females), all females survived exposure to the test substance; Body weight gain was unaffected by the administration of the

test substance; All animals appeared normal for the duration of the study; The gross necropsy at the conclusion of the study revealed no observable abnormalities. At 1000, 2000, 3000 and 5050 mg/kg dose levels mortality was as follows: at 1000 mg/kg dose level (5/sex), 2 females died within 3 days of test substance administration; at 2000 mg/kg dose level (5/sex), three males and 1 female died within 5 days of test substance administration; at 3000 mg/kg dose level (5 females), 3 females died within 6 days of test substance administration; at 5050 mg/kg dose level (5/sex), all animals died within 6 days of test substance administration. Prominent in-life observations for 1000, 2000, 3000 and 5050 mg/kg dose levels included alopecia (through day 14), activity decrease, anus red and swollen, crusted muzzle and eyes, diarrhea and soft feces, decreased defecation, respiratory chirp gurgle, piloerection, ptosis, polyuria, salivation, swollen face, sensitivity to touch, stained fur, withdrawn testes and walking on tiptoe, which were no longer evident in surviving animals by Day 13. Ataxia, nasal and ocular discharge, distended abdomen and gasping were observed only in animals that died on test. Body weight gain in surviving animals was largely unaffected by the administration of the test substance. One of seven males and three of nine females lost or failed to gain weight between days 0 and 7. The gross necropsy on animals that died on test revealed matted and stained fur; discolored lungs, spleen and liver; thickened stomach mucosa; gas and discolored contents in the gastrointestinal tract. The gross necropsy in animals surviving to termination of the study revealed no observable abnormalities, except alopecia in the genital area of three animals.

B. ACUTE TOXICITY VALUE (LD50, LC50, etc.): LD50 (M/F) is > 500 mg/kg but < 2000 mg/kg

C. TOXICITY CATEGORY: III

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). What are they and can they be corrected with additional information? none **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? no **Are there any recommendations specific to this study?:** none

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
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TOXICOLOGY STUDY EVALUATION WORKSHEET

I. STUDY IDENTIFICATION

Active Ingredient: 1. 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; 2. n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{16}) dimethyl benzyl ammonium chloride; 3. octyl decyl dimethyl ammonium chloride; 4. didecyl dimethyl ammonium chloride; 5. dioctyl dimethyl ammonium chloride
Formulated Product Name: AM 3651P
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5. 1710 **ID #:** 269397
Document #: 53139-0013 **Record #:** 283718
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Full Study Title: ACUTE DERMAL TOXICITY STUDY IN RABBITS
Company Sponsor: BioShield Technologies, Inc., Norcross, GA
Conducting Laboratory: Stillmeadow, Inc., Sugar Land, TX
Final Report Date: 04/21/99
Study Interval: 1/07/99-3/04/99

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? -No
Is study acceptable? -No

- **Meets EPA guidelines**
- **Minor variances from guidelines**
Yes - **Major variances from guidelines**
No - **Could be upgraded with additional information (see VI-A)**

Yes - **Has useful data**
- **Insufficient data**
- **Non EPA validated study**
- **Other**_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?: no

C. ONE LINER-One or two sentence summary of the study:
53139-0013 283718; Acute dermal toxicity; 812; Rabbit; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4851-98; 04/21/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered to 5 males and 20 female rabbits. The rabbits were dosed at 5050 (5/sex), 5500 (5 F), 3500 (5 F), and 500 (5 F) mg/kg dose levels, 24-hour exposure, occlusive wrap. Clinical observations: At 500 mg/kg dose level (5 females), all females survived exposure to the test substance; Body weight gain was unaffected by the administration of the test substance; All animals appeared normal for the duration of the study; The gross necropsy at the conclusion of the study revealed no observable abnormalities. At 3500 (5 females) and at 5050 (5/sex) mg/kg dose level, two female deaths were noted at each dose level. At 5500 mg/kg dose level (5 females), no mortality was noted. Prominent in-life observations for 3500, 5050 and 5500 mg/kg dose levels included diarrhea and soft feces, decreased and no defecation, and not

eating. Surviving animals were asymptomatic by Day 4, except for one animal with decreased defecation on Day 12. Dermal irritation in animals at all dose levels included very slight to severe erythema, very slight to moderate edema, atonia, coriaceousness, desquamation, eschar and/or necrosis. Body weight gain in several surviving animals was affected by the administration of the test substance. Four of five males and six of eleven females lost or failed to gain weight between Days 0 and 7. Gross necropsy in animals that died on test revealed ocular and nasal discharge, hemorrhage around eye, discolored abdominal skin, lungs discolored and having lesions, stomach wall and liver friable; fluid in the abdomen and gas in the intestines. Gross necropsy in animals surviving to termination of the study revealed no observable abnormalities. There were two female deaths each at 3500 and 5050 mg/kg dose levels, and no deaths at 5500 mg/kg dose level. Hence, a dose response relationship for females was not established; Study Unacceptable, Not Upgradable. (Mehta, 06/26/15)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?: No

Staff Toxicologist **Date**

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Albino Rabbit
Strain: New Zealand white
Source of animals: Ray Nichols Rabbitry, Lumberton, TX
Age at start: Approximately 16 week old; 5 males and 20 females; Females were nulliparous and non-pregnant; Males weighing 2300-2900 grams and females weighing 2075-3350 grams on day of dosing.
Route of administration: Dermal application
Vehicle: none: test article was used as received
Period of treatment: 24-hour exposure, 14-day observation period

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

Dosing Sequence	Dose Level (mg/kg)	Number of animals		Mortality (number dead/number treated)	
		Females	Males	Females	Males
1	5050	5	5	2/5	0/5
2	5500	5	-	0	-
2	3500	5	-	2/5	-
3	500	5	-	0/5	-

IV. STUDY DESIGN AND EVALUATION

A. STUDY PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** AM 3651P; Composition: 55.2% total quaternary ammonium chloride; Batch#: B129828B-2 and B129828B-3. Physical properties: pale yellow liquid, date of received: 01/04/99 and 01/06/99, stored at room temperature. Expiration: 12/29/99.

*2. **Analysis of dosing material:** The test article was applied as received. Purity of test substance was provided as 55.2% total quaternary ammonium chloride. Records pertaining to identity, synthesis methods and location of documentation are the responsibility of the sponsor. A certificate of analysis specifying purity of test substance was not provided. Stability details were not provided. These are considered minor deficiencies and had no impact on study outcome.

3. **Animal selection:** OK
4. **Animal husbandry:** Animal room temperature and relative humidity ranges were maintained at 22±3°C and 30-70%, respectively.
5. **Mortality:** OK
6. **Number of animals:** OK
7. **Randomization of animals:** OK
8. **Dose level selection:** OK
9. **Route of administration:** OK; Dermal
10. **Exposure conditions:** OK
11. **Controls:** NA
12. **Observations:** Animals were observed for mortality and clinical/behavioral signs of toxicity at least three times on day of dosing (Day 0) and at least once daily thereafter for 14 days; body weights were recorded prior to dosing and on day 7 and 14, or at the time of discovery after death. Observations for evidence of dermal irritation were made at approximately 60 minutes after removal of wrappings, and on days 4, 7, 11 and 14.
13. **Necropsies:** OK
14. **Appropriateness of methods:** OK

*15. **Treatment of results:** There were two female deaths each at 3500 and 5050 mg/kg dose levels, and no deaths at 5500 mg/kg dose level. Hence, a dose response relationship for females was not established. This is considered a major deficiency and will have an impact on study outcome (see section VI.A)

*16. **Test report:** on page # 14, the 5500 dose level is mistyped as 5550 mg/kg. This is considered a minor deficiency and had no impact on study outcome.

17. **Consistency:** OK
18. **Good Laboratory Practice:** GLP compliance statement and quality assurance audit record included in the report.
19. **Other:** NA

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED: At 500 mg/kg dose level (5 females), all females survived exposure to the test substance; Body weight gain was unaffected by the administration of the test substance; All animals appeared normal for the duration of the study; The gross necropsy at the conclusion of the study revealed no observable abnormalities. At 3500 (5 females) and at 5050 (5/sex) mg/kg dose level, two female deaths were noted at each dose level. At 5500 mg/kg dose level (5 females), no mortality was noted. Prominent in-life observations for 3500, 5050 and 5500 mg/kg dose levels included diarrhea and soft feces, decreased and no defecation, and not eating. Surviving animals were asymptomatic by Day 4, except for one animal with decreased defecation on Day 12. Dermal irritation in animals at all dose levels included very slight to severe erythema, very slight to moderate edema, atonia, coriaceousness, desquamation, eschar and/or necrosis. Body weight gain in several surviving animals was affected by the administration of the test substance. Four of five males and six of eleven females lost or failed to gain weight between Days 0 and 7. Gross necropsy in animals that died on test revealed ocular and nasal discharge, hemorrhage around eye, discolored abdominal skin, lungs discolored and having lesions, stomach wall and liver friable; fluid in the abdomen and gas in the intestines. Gross necropsy in animals surviving to termination of the study revealed no observable abnormalities.

B. ACUTE TOXICITY VALUE (LD50, LC50, etc.): Not established

C. TOXICITY CATEGORY: II (see section VI)

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). What are they and can they be corrected with additional information? Yes **Be specific:** although, there were no female mortalities at 5500 mg/kg dose level, there were two female deaths each at 3500 and at 5050 mg/kg dose levels. Therefore, a dose response relationship could not be established. This is considered a major deficiency. The study is unacceptable and not upgradable.

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? no **Are there any recommendations specific to this study?:** Although unacceptable and not upgradable, study supports Toxicity Category II acute dermal toxicity.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
HUMAN HEALTH ASSESSMENT BRANCH
TOXICOLOGY STUDY EVALUATION WORKSHEET

I. STUDY IDENTIFICATION

Active Ingredient: 1. 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; 2. n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{16}) dimethyl benzyl ammonium chloride; 3. octyl decyl dimethyl ammonium chloride; 4. didecyl dimethyl ammonium chloride; 5. dioctyl dimethyl ammonium chloride
Formulated Product Name: AM 3651P
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5. 1710 **ID #:** 269397
Document #: 53139-0014 **Record #:** 283719
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Study Type: 813-Acute Inhalation Toxicity
Full Study Title: ACUTE INHALATION TOXICITY STUDY IN RATS
Company Sponsor: BioShield Technologies, Inc., Norcross, GA
Conducting Laboratory: Stillmeadow, Inc., Sugar Land, TX
Final Report Date: 04/26/99
Study Interval: 01/14/99-02/09/99

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? -No
Is study acceptable? -Yes

- **Meets EPA guidelines**
- Yes - **Minor variances from guidelines**
- **Major variances from guidelines**
- **Could be upgraded with additional information (see VI-A)**

Yes - **Has useful data**
- **Insufficient data**
- **Non EPA validated study**
- **Other**_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?: No

C. ONE LINER-One or two sentence summary of the study:
53139-0014 283719; Acute inhalation toxicity; 813; Rat; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4852-98; 04/26/99; Bennick, J. E., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered to 5 animals/sex at 3.19 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 2.7 µm (3.15); 5 animals/sex at 1.42 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 2.3 µm (7.3); 5 animals/sex at 0.95 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 3.6 µm (4.25); 5 males at 0.72 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 1.5 µm (3.6), 4-hour nose-only exposure. Clinical observation: Mortality at each dose level was as follows (number dead/number treated in parenthesis): at 0.72 mg/L (1/5 males), at 0.95 mg/L (2/5 males, 1/5 females), at 1.42 mg/L (4/5 males, 2/5 females), and at 3.19 mg/L (3/5 males, 3/5 females).

Prominent in-life observations included aggression, crusted eyes/nose, decreased defecation, gasping, piloerection, ptosis and sensitivity to touch, which were no longer evident in surviving animals by day 8. Activity decreases and respiratory gurgle were observed through Day 14. Discolored eye, polyuria and withdrawn testes were observed only in one animal that died on test. Abnormal necropsy findings in animals that died on test pertained to crusted eyes/nose/mouth; discolored and swollen lungs, discolored stomach and contents, and gas in the gastrointestinal tract. The gross necropsy conducted on each animal surviving to termination of the study revealed no observable abnormalities, except discolored lungs in three animals. LC50 (M) is 1.32 mg/L with 95% confidence interval of 0.53 to 3.35 mg/L, and LC50 (F) is 2.24 mg/L with 95% confidence interval of 0.97 to 5.20 mg/L; Toxicity Category III; Study Acceptable. (Mehta, 06/29/15)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?: Yes

Staff Toxicologist **Date**

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Rat
Strain: HSD: Sprague-Dawley
Source of animals: Harlan Sprague Dawley, Inc., Indianapolis, IN
Age at start: Approximately 8 weeks old; Sex: 20 males and 15 females; Weight: males weighing 237-354 grams and females weighing 181-228 grams on day of dosing. Females were nulliparous and non-pregnant.
Route of administration: Inhalation, nose-only exposure
Vehicle: none
Period of treatment: 4-hour exposure, 14-day observation period

B. BACKGROUND (including relationship of this study to other studies): Trial assays were conducted to determine methods of aerosolizing the test substance into the exposure chamber to produce an acceptable concentration and mass median aerodynamic diameter (MMAD).

C. TREATMENT LEVELS AND GROUP SIZE:

Dosing Sequence	Dose Level (mg/L)	Number of animals		Mortality (number dead/number treated)	
		Females	Males	Females	Males
1	3.19	5	5	3/5	3/5
2	1.42	5	5	2/5	4/5
3	0.95	5	5	1/5	2/5
4	0.72	-	5	-	1/5

IV. STUDY DESIGN AND EVALUATION

A. STUDY PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

*1. **Test article:** AM 3651P; Composition: 55.2% total quaternary ammonium chloride; Batch#: B129828B-2 and B129828B-3. Physical properties: pale yellow liquid, date of received: 01/04/99 and 01/06/99, stored at room temperature. Expiration: 12/29/99. The test article was applied as received. Purity of test substance was provided as 55.2% total quaternary ammonium chloride. Records pertaining to identity, synthesis methods and location of documentation are the responsibility of the sponsor. A certificate of analysis specifying purity of test substance was not provided. Stability details were not provided. These are considered minor deficiencies and had no impact on study outcome.

2. **Analysis of dosing material:** The animals were exposed to an aerosol generated from undiluted liquid test substance. The concentration of the test substance in the exposure atmosphere was determined gravimetrically twice per hour and nominally at the end of the exposure. The gravimetric concentration was determined by passing a known volume of exposure air through a pre-weighed filter and dividing the amount of test substance deposited on the filter by the volume of air that passed through the filter. A cascade impactor was used to assess the particle size distribution of the test atmosphere by withdrawing samples from the breathing zone of the animals at two intervals. The collections were carried out for 30 seconds at airflows of 7.3 Lpm.
3. **Animal selection:** OK
4. **Animal husbandry:** Animal room temperature and relative humidity ranges were maintained at 22±3°C and 30-70%, respectively.
5. **Mortality:** OK
6. **Number of animals:** OK
7. **Randomization of animals:** OK
8. **Dose level selection:** OK
9. **Route of administration:** OK
10. **Exposure conditions:** A 500 L nose-only stainless steel, dynamic flow inhalation chamber was utilized in this study. 5 animals/sex at 3.19 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 2.7 µm (3.15); 5 animals/sex at 1.42 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 2.3 µm (7.3); 5 animals/sex at 0.95 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 3.6 µm (4.25); 5 males at 0.72 mg/L exposure concentration (gravimetric), with mean MMAD (GSD) 1.5 µm (3.6), 4-hour nose-only exposure.
11. **Controls:** NA
12. **Observations:** Animals were observed frequently for pharmacological and /or toxicological effects on the day of dosing (Day 0) and at least once daily thereafter for 14 Days; individual body weights were recorded just prior to inhalation exposure and on Days 7 and 14. On Day 14 post-exposure, all animals were subjected to gross necropsy.
13. **Necropsies:** OK
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK

16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** GLP compliance statement and quality assurance audit records were included in the report.
19. **Other:** NA

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED: Mortality at each dose level was as follows (number dead/number treated in parenthesis): at 0.72 mg/L (1/5 males), at 0.95 mg/L (2/5 males, 1/5 females), at 1.42 mg/L (4/5 males, 2/5 females), and at 3.19 mg/L (3/5 males, 3/5 females). Prominent in-life observations included aggression, crusted eyes/nose, decreased defecation, gasping, piloerection, ptosis and sensitivity to touch, which were no longer evident in surviving animals by day 8. Activity decreases and respiratory gurgle were observed through Day 14. Discolored eye, polyuria and withdrawn testes were observed only in one animal that died on test. Abnormal necropsy findings in animals that died on test pertained to crusted eyes/nose/mouth; discolored and swollen lungs, discolored stomach and contents, and gas in the gastrointestinal tract. The gross necropsy conducted on each animal surviving to termination of the study revealed no observable abnormalities, except discolored lungs in three animals.

B. ACUTE TOXICITY VALUE (LD50, LC50, etc.): LC50 (M) is 1.32 mg/L with 95% confidence interval of 0.53 to 3.35 mg/L, and LC50 (F) is 2.24 mg/L with 95% confidence interval of 0.97 to 5.20 mg/L.

C. TOXICITY CATEGORY: III

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). What are they and can they be corrected with additional information? none **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? no **Are there any recommendations specific to this study?:** none

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
HUMAN HEALTH ASSESSMENT BRANCH
TOXICOLOGY STUDY EVALUATION WORKSHEET

I. STUDY IDENTIFICATION

Active Ingredient: 1. 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; 2. n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{16}) dimethyl benzyl ammonium chloride; 3. octyl decyl dimethyl ammonium chloride; 4. didecyl dimethyl ammonium chloride; 5. dioctyl dimethyl ammonium chloride
Formulated Product Name: AM 3651P
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5. 1710 **ID #:** 269397
Document #: 53139-0015 **Record #:** 283720
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Study Type: 814-Primary Eye Irritation
Full Study Title: PRIMARY EYE IRRITATION STUDY IN RABBITS
Company Sponsor: BioShield Technologies, Inc., Norcross, GA
Conducting Laboratory: Stillmeadow, Inc., Sugar Land, TX
Final Report Date: 03/31/99
Study Interval: 01/11/99-02/01/99

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? -No
Is study acceptable? -Yes

- **Meets EPA guidelines**
- Yes - **Minor variances from guidelines**
- **Major variances from guidelines**
- **Could be upgraded with additional information (see VI-A)**

Yes - **Has useful data**
- **Insufficient data**
- **Non EPA validated study**
- **Other**_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?: Yes; Category I eye irritant

C. ONE LINER-One or two sentence summary of the study:
53139-0015 283720; Acute Eye Irritation; 814; Rabbit; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4853-98; 03/31/99; Kuhn, J.O., AM 3651P (a.i.: 55.2% total quaternary ammonium chloride) was administered to 3 male and 6 female (3 unwashed and 3 washed) rabbits by ocular instillation, Dose: 0.1 ml in the right eye. Observations: For unwashed eyes, "positive" effects persisted through Day 21 post-instillation. One animal/sex exhibited pain (squealing) at the time of treatment. Opacity: from 24 hours to day 21 post-instillation 6/6 treated eyes couldn't be scored due to chemosis and/or discharge. Conjunctival redness: on day 21, 2/6 treated eyes showed score 2 redness and 4/6 treated eyes couldn't be scored due to chemosis and/or discharge; in addition, 5/6 animals showed moderate and 1/6 animals showed severe alopecia around the eye. Chemosis: on day 21 post-instillation, 3/6 treated eyes had score 3, 2/6

treated eyes had score 2, and 1/6 treated eyes had score 4 chemosis. Discharge: on day 21 post-instillation, 5/6 treated eyes showed score 2, and 1/6 treated eyes showed score 3 discharge. Necrosis was evident in 6/6 treated eyes up to 24 hours post-instillation. For washed eyes, "positive" effects persisted through Day 21 post-instillation. Opacity: on day 21 post-instillation, 1/3 treated eyes showed score 4 opacity, with apparent invasion of cornea by blood vessels, and 2/3 treated eyes couldn't be scored due to chemosis and/or discharge. Conjuctival redness: on day 21 post-instillation, 2/3 treated eyes showed score 3, and 1/3 treated eyes showed score 2 redness; moderate alopecia around the eye was noted for one treated eye. Chemosis: at 21 days post-instillation, 1/3 treated eyes showed score 3, and 2/3 treated eyes showed score 2 chemosis. Discharge: at 21 days post-instillation, 3/3 treated eyes showed score 2 discharge. Toxicity Category I; Study Acceptable. (Mehta, 06/30/15)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?: Yes

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Staff Toxicologist **Date**

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Rabbit
Strain: New Zealand White
Source of animals: Ray Nichols Rabbitry, Lumberton, TX
Age at start: Young adult, approximately 15 week old, Sex: 3 males and 3 females (unwashed); 3 females (washed); males weighing: 2275-2975 grams and females weighing 2275-2725 grams.
Route of administration: Ocular instillation
Vehicle: none
Period of treatment: Single dose, 72-hour observation period

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

	Units (0.1 ml/eye)
#Males:	3 (unwashed)
#Females:	6 (3 unwashed and 3 washed)

IV. STUDY DESIGN AND EVALUATION

A. STUDY PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** AM 3651P; Composition: 55.2% total quaternary ammonium chloride; Batch#: B129828B-2 and B129828B-3. Physical properties: pale yellow liquid, date of

received: 01/04/99 and 01/06/99, stored at room temperature. pH: 6.96. Expiration: 12/29/99.

*2. **Analysis of dosing material:** The undiluted test article was instilled as received. Purity of test substance was provided as 55.2% total quaternary ammonium chloride. Records pertaining to identity, synthesis methods and location of documentation are the responsibility of the sponsor. A certificate of analysis specifying purity of test substance was not provided. Stability details were not provided. These are considered minor deficiencies and had no impact on study outcome.
3. **Animal selection:** OK
4. **Animal husbandry:** Animal room temperature and relative humidity ranges were maintained at 20±3°C and 30-70%, respectively.
5. **Mortality:** NA
6. **Number of animals:** OK
7. **Randomization of animals:** Both eyes of each animal were determined to be free of defects prior to inclusion of the animal in the study.
8. **Dose level selection:** OK; On Day 0, a dose of 0.1 mL of the undiluted test substance was placed into the conjuctival sac of the right eye. Three of the treated eyes ('washed eyes") were each washed with room temperature deionized water for one minute beginning 30 seconds after treatment.
9. **Route of administration:** OK
10. **Exposure conditions:** OK
11. **Controls:** Contralateral eye
12. **Observations:** Ocular irritation scores were recorded at 1, 24, 48 and 72 hours and at 4, 7, 10, 14, 17 and 21 days post-instillation.
13. **Necropsies:** NA
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** GLP compliance statement and quality assurance audit record included in the report.
19. **Other:** NA

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED: <u>For unwashed eyes,</u> "positive" effects persisted through Day 21 post-instillation. One animal/sex exhibited pain (squealing) at the time of treatment. Opacity: from 24 hours to day 21 post-instillation 6/6 treated eyes couldn't be scored due to chemosis and/or discharge. Conjunctival redness: on day 21, 2/6 treated eyes showed score 2 redness and 4/6 treated eyes couldn't be scored due to chemosis and/or discharge; in addition, 5/6 animals showed moderate and 1/6 animals showed severe alopecia around the eye. Chemosis: on day 21 post-instillation, 3/6 treated eyes had score 3, 2/6 treated eyes had score 2, and 1/6 treated eyes had score 4 chemosis. Discharge: on day 21 post-instillation, 5/6 treated eyes showed score 2, and 1/6 treated eyes showed score 3 discharge. Necrosis was

evident in 6/6 treated eyes up to 24 hours post-instillation. For washed eyes, "positive" effects persisted through Day 21 post-instillation. Opacity: on day 21 post-instillation, 1/3 treated eyes showed score 4 opacity, with apparent invasion of cornea by blood vessels, and 2/3 treated eyes couldn't be scored due to chemosis and/or discharge. Conjuctival redness: on day 21 post-instillation, 2/3 treated eyes showed score 3, and 1/3 treated eyes showed score 2 redness; moderate alopecia around the eye was noted for one treated eye. Chemosis: at 21 days post-instillation, 1/3 treated eyes showed score 3, and 2/3 treated eyes showed score 2 chemosis. Discharge: at 21 days post-instillation, 3/3 treated eyes showed score 2 discharge.

B. ACUTE TOXICITY VALUE (LD50, LC50, etc.): NA

C. TOXICITY CATEGORY: I

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). What are they and can they be corrected with additional information? None **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? Yes; Toxicity Category I eye irritant **Are there any recommendations specific to this study?:** None

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
HUMAN HEALTH ASSESSMENT BRANCH
TOXICOLOGY STUDY EVALUATION WORKSHEET

I. STUDY IDENTIFICATION

Active Ingredient: 1. 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; 2. n-alkyl (50%C_{14}, 40%C_{12}, 10%C_{16}) dimethyl benzyl ammonium chloride; 3. octyl decyl dimethyl ammonium chloride; 4. didecyl dimethyl ammonium chloride; 5. dioctyl dimethyl ammonium chloride
Formulated Product Name: AM 3651P
Chemical Code #: 1. 6053; 2. 1846; 3. 1709; 4. 1682; 5.1710 **ID #:** 269397
Document #: 53139-0016 **Record #:** 283721
EPA Reg. #: 87583-5-90638 **SB 950 #:** NA
Study Type: 815; PRIMARY DERMAL IRRITATION STUDY IN RABBITS
Full Study Title: ACUTE DERMAL IRRITATION IN RABBITS
Company Sponsor: BioShield Technologies, Inc., Norcross, GA
Conducting Laboratory: Stillmeadow, Inc., Sugar Land, TX
Final Report Date: 03/31/99
Study Interval: 01/12/99-01/26/99

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? -No
Is study acceptable? -Yes

- **Meets EPA guidelines**
- Yes - **Minor variances from guidelines**
- **Major variances from guidelines**
- **Could be upgraded with additional information (see VI-A)**

Yes - **Has useful data**
- **Insufficient data**
- **Non EPA validated study**
- **Other**_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?: No

C. ONE LINER-One or two sentence summary of the study:
53139-0016 283721; Acute Dermal Irritation Study; 815; Rabbits; Stillmeadow, Inc., Sugar Land, TX; Report/Study# 4854-98; 03/31/99; Kuhn, J.O., The skin of 3 males and 3 female New Zealand albino rabbits was exposed to 0.5 ml of AM 3651P (a.i.: 55.2% total quaternary ammonium chloride)/site, one site/animal, for 4 hours under a semi-occlusive wrap. Erythema: at 1 hour post-application, 5/6 animals showed score 2, and 1/6 animals showed score 1 erythema; from 24 hours to day 7 post-application 6/6 treated sites showed score 2 erythema; day 10 post-application, 5/6 sites showed score 2 and 1/6 treated sites showed score 1 erythema; day 14 post-application, 2/6 treated sites showed score 4, 2/6 sites showed score 2, and 2/6 sites showed score 1 erythema. Edema: at 1 hour post-application, 3/6 rabbits showed score 1, 2/6 sites showed score 2, and 1/6 sites showed score 3 edema; at 24 hours post-application, 3/6 sites showed score 1, and 3/6 sites showed score 2 edema; at 48 and at 72 hours post-application, 5/6 sites showed score 1 edema; at day 7 and at day 10 post-application, 3/6 sites showed score 1

edema; at day 14 post-application, 1/6 rabbits showed score 1 edema. **Toxicity Category I** (severe erythema (score 4) persisted up to study termination); Study Acceptable. (Mehta, 06/30/15)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?: Yes

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Staff Toxicologist **Date**

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Albino Rabbit
Strain: New Zealand White
Source of animals: Ray Nichols Rabbitry, Lumberton, TX
Age at start: Young adult approximately 12 week old; Sex: 3 males and 3 females; Males weighing: 2550-3000 grams and females weighing 2550-3100 grams.
Route of administration: Dermal application
Vehicle: none
Period of treatment: 4-hour exposure, 72-hour observation period

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

	Units (0.5 ml/site)
#Males:	3
#Female:	3

IV. STUDY DESIGN AND EVALUATION

A. STUDY PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** AM 3651P; Composition: 55.2% total quaternary ammonium chloride; Batch#: B129828B-2 and B129828B-3. Physical properties: pale yellow liquid, date of received: 01/04/99 and 01/06/99, stored at room temperature. pH: 6.96. Expiration: 12/29/99.

*2. **Analysis of dosing material:** The undiluted test article was applied as received. Purity of test substance was provided as 55.2% total quaternary ammonium chloride. Records pertaining to identity, synthesis methods and location of documentation are the responsibility of the sponsor. A certificate of analysis specifying purity of test substance was not provided. Stability details were not provided. These are considered minor deficiencies and had no impact on study outcome.

3. **Animal selection:** OK
4. **Animal husbandry:** Animal room temperature and relative humidity ranges were maintained at 20±3°C and 30-70%, respectively.
5. **Mortality:** NA

6. **Number of animals:** OK
7. **Randomization of animals:** Animals with exposure areas free of pre-existing skin irritation or defects were selected for testing.
8. **Dose level selection:** OK, 0.5 ml of test substance was applied to the test site.
9. **Route of administration:** OK
10. **Exposure conditions:** OK
11. **Controls:** NA
12. **Observations:** Dermal irritation scores were recorded at 1, 24, 48 and 72 hours and on Days 7, 10 and 14 post-exposure.
13. **Necropsies:** NA
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** GLP compliance statement and quality assurance audit record included in the report.
19. **Other:** NA

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED: Erythema: at 1 hour post-application, 5/6 animals showed score 2, and 1/6 animals showed score 1 erythema; from 24 hours to day 7 post-application 6/6 treated sites showed score 2 erythema; day 10 post-application, 5/6 sites showed score 2 and 1/6 treated sites showed score 1 erythema; day 14 post-application, 2/6 treated sites showed score 4, 2/6 sites showed score 2, and 2/6 sites showed score 1 erythema. Edema: at 1 hour post-application, 3/6 rabbits showed score 1, 2/6 sites showed score 2, and 1/6 sites showed score 3 edema; at 24 hours post-application, 3/6 sites showed score 1, and 3/6 sites showed score 2 edema; at 48 and at 72 hours post-application, 5/6 sites showed score 1 edema; at day 7 and at day 10 post-application, 3/6 sites showed score 1 edema; at day 14 post-application, 1/6 rabbits showed score 1 edema.

B. ACUTE TOXICITY VALUE (LD50, LC50, etc.): See Section VI. B

C. TOXICITY CATEGORY: I

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). What are they and can they be corrected with additional information? None **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? No **Are there any recommendations specific to this study?:** Although the reported PDII was 3.2, persistence of severe erythema (score 4) up to study termination prompted a Toxicity Category I designation.

KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
E-mail: kevinkutcel@gmail.com

October 13, 2015

US EPA (NOTIF)
Office of Pesticide Programs
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Notification per California Department of Pesticide Regulation (EPA No. 87583-5)

In their review of the label, the California Department of Pesticide Regulation has requested that PureShield Inc. file a notification with the US EPA with the following changes to the label:

- Removal of all fungicidal/fungistatic and algicidal/algistatic claims on the label.
- Update the nomenclature from *Salmonella choleraesius* to *Salmonella enterica.*
- Correct the typo that clarifies the claim as "an antimicrobial agent."
- Amend the language in the precautionary statement that correctly identifies the Toxicity Category I primary skin irritation hazard and the Toxicity category II acute dermal toxicity hazard.

Please accept the attached one copy of the revised label for Reg. No. 87583-5 showing the highlighted changes and three (3) copies of the revised label.

Attached is EPA Form 8570-1 regarding this notification as required in PR Notice 1998-10. This notification is consistent with the guidance in PR Notice 1998-10 and the requirements of EPA's regulations at 40 CFR 156.46, 156.140, 156.144, 156,146 and 156.156 and no other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand this it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of PR Notice 98-10 and CFR 156.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Please note that KRK Consulting LLC is the authorized agent handling all correspondence for PureShield Inc. and therefore all responses should be directed to the contact information on the letterhead above.

Best Regards,

Kevin R. Kutcel,
Agent for PureShield Inc.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
PureShield, Inc. / 87583-5		☒ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
PureShield, Inc. / Bio-Protect DP	31	

5. Name and Address of Applicant *(Include ZIP Code)*

PureShield Inc.
1445 Jupiter Park, Suite 11
Jupiter, FL 33458

☒ *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Please see cover letter.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container		☒ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☒ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

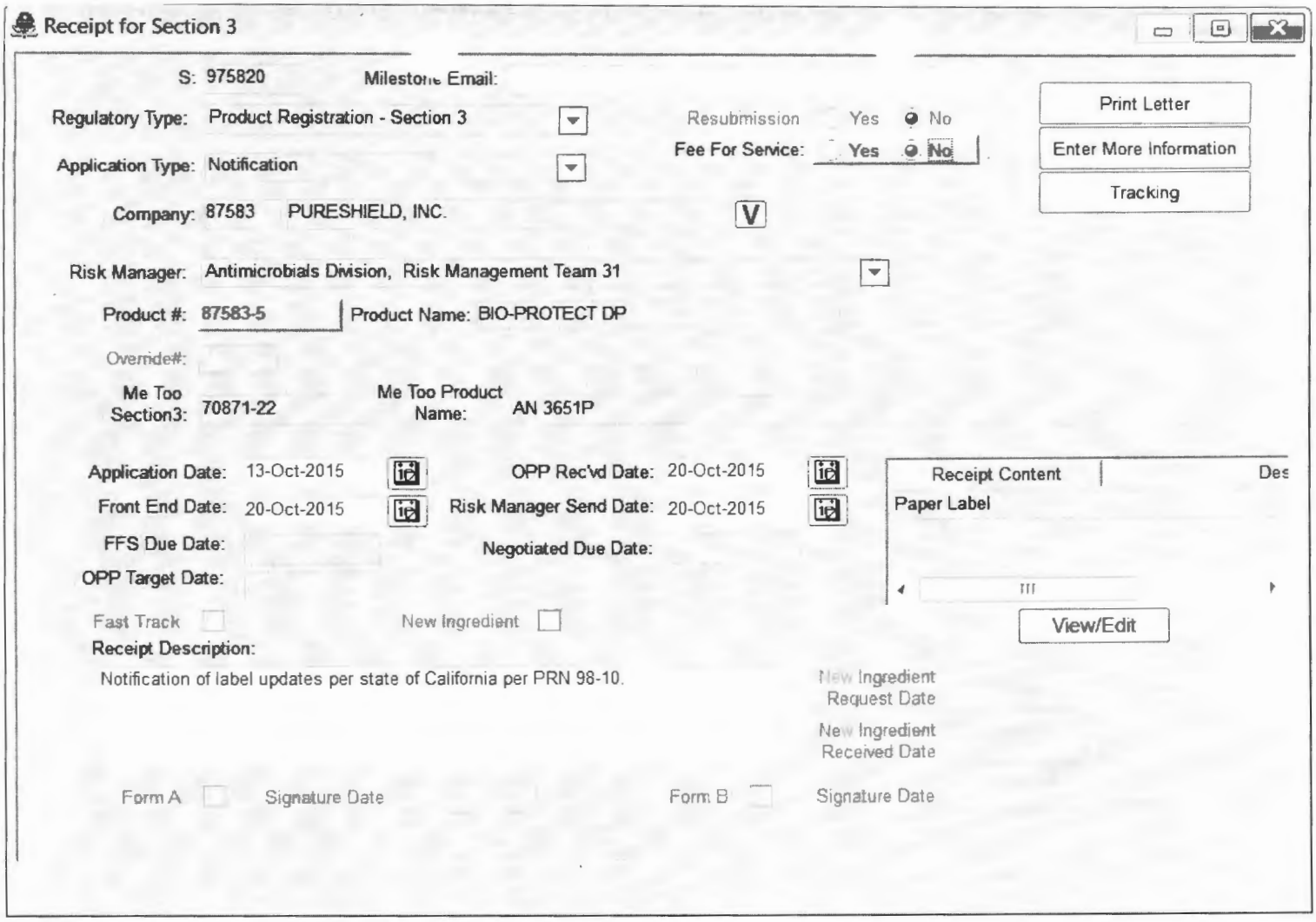
Name	Title	Telephone No. (Include Area Code)
Kevin Kutcel	Agent	440-263-7305

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
	Agent
4. Typed Name	**5. Date**
Kevin R. Kutcel	Oct 13, 2015


Receipt for Section 3
S: 975820
Milestone Email:
Regulatory Type: Product Registration - Section 3
Application Type: Notification
Company: 87583 PURESHIELD, INC.
Resubmission Yes No
Fee For Service: Yes No
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 31
Product #: 87583-5
Product Name: BIO-PROTECT DP
Override#:
Me Too Section3: 70871-22
Me Too Product Name: AN 3651P
Application Date: 13-Oct-2015
OPP Rec'vd Date: 20-Oct-2015
Front End Date: 20-Oct-2015
Risk Manager Send Date: 20-Oct-2015
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Paper Label
View/Edit
Fast Track
New Ingredient
Receipt Description:
Notification of label updates per state of California per PRN 98-10.
New Ingredient Request Date
New Ingredient Received Date
Form A
Signature Date
Form B
Signature Date

Please read instructions on reverse before comp form. Form Approved, O o. 2070-0060 Print Form

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
PureShield, Inc. / 87583-5	Velma Noble	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
PureShield, Inc. / Bio-Protect DP	31	

5. Name and Address of Applicant *(Include ZIP Code)*

PureShield Inc.
1445 Jupiter Park, Suite 11
Jupiter, FL 33458

[X] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[X] Final printed labels in response to Agency letter dated 11/3/2011
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[X] Yes* [ ] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information
[X] Label [ ] Container

4. Size(s) Reteil Container
2, 4, 8, 16, 20, 22, 36 fl oz
1, 5, 55, 150, 300 gallons

5. Location of Label Directions
[X] On Label
[ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
[X] Lithograph / Paper glued / Stenciled
[ ] Other _____

Section - IV

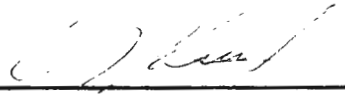
1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Kevin Kutcel	Consultant	440-263-7305

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature	3. Title
	Consultant
4. Typed Name	**5. Date**
Kevin R. Kutcel	Nov 11, 2011

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

BIO-PROTECT DP

DISINFECTANT and ANTIMICROBIAL AGENT
A Silicone Quaternary Ammonium Salt

Active Ingredients:	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride	36.60%
	n-alkyl (50% C_{14}, 40% C_{12}, 10% C_{18}) dimethyl benzyl ammonium chloride	6.40%
	Octyl decyl dimethyl ammonium chloride	4.80%
	Didecyl dimethyl ammonium chloride	2.88%
	Dioctyl dimethyl ammonium chloride	1.92%
Other Ingredients:		48.40%
TOTAL INGREDIENTS:		100.00%

Contains over 6% methanol

EPA Reg. No. 87583-5 **KEEP OUT OF REACH OF CHILDREN** EPA EST – XXXXX-XX-XX

DANGER [redacted] POISON

NET CONTENTS: 2, 4, 8, 16, 20, 22, OR 36 fluid oz.; 1, 5, 55, 150, or 300 gal. Lot No. ___ _____

FIRST AID

Have the product container or label with you when calling the poison control center or doctor, or going for treatment.

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call poison control center or doctor for treatment advice.
- Methanol may cause blindness.

IF INHALED:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

IF ON SKIN:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER! Corrosive: Methanol may cause blindness. Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing spray mist. Wear protective eyewear (goggles or face shield). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame. De-activation of BIO-PROTECT DP can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of BIO-PROTECT DP.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

De-activation may be required during clean up if a spill occurs. De-activation of BIO-PROTECT DP can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of BIO-PROTECT DP.

DIRECTIONS FOR USE
For use in homes, offices, and institutions (schools, daycare centers, churches, correctional facilities)

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Allow treated areas and surfaces to dry before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application.

BIO-PROTECT DP is an effective disinfectant against *Salmonella choleraesuis*, and *Staphylococcus aureus*. BIO-PROTECT DP is also effective against odor-causing bacteria, bacteria that causes staining and discoloration, fungi (mold and mildew) and algae as a static agent.

BIO-PROTECT DP may be used for treatment of the following hard non-porous surfaces to impart disinfection (*Salmonella choleraesuis* and *Staphylococcus aureus*), bacteriostatic/fungistatic/algaestatic, and deodorizing activity:

	Pest controlled	Dilution Rate	Method of Application
Tubs, glazed tiles, vanity tops, shower stalls (areas), sinks, washable walls, vinyl wall paper for non-food contact, floors, window sills, cabinets, garbage cans, exterior surfaces of appliances and refrigerators	Odor-causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), *Salmonella choleraesuis* and *Staphylococcus aureus*	0.5 oz/gallon	**SPRAY**: Dilute BIO-PROTECT DP in water; mix well. Using a trigger pump sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. **For Disinfecting:** Let stand for 10 minutes, then wipe surface dry.

MOLD, MILDEW, ODOR PROTECTOR, ODOR INHIBITOR, AND KILLER
BIO-PROTECT DP is an antimicrobial agent effective against microorganisms that cause offensive odors on hard, non-porous surfaces.
BIO-PROTECT DP is an antimicrobial agent effective against odor-causing bacteria in the kitchen and bathroom.
BIO-PROTECT DP is an antimicrobial agent effective in controlling mold and mildew, and inhibiting the growth of mold and mildew.
BIO-PROTECT DP, and antimicrobial agent, disinfects hard, non-porous surfaces and kills *Salmonella choleraesuis* and *Staphylococcus aureus*.
BIO-PROTECT DP, and antimicrobial agent, can be used in and around bathtubs and shower stalls to prevent the growth of mold and mildew.
BIO-PROTECT DP provides an invisible barrier to inhibit the growth of odor-causing bacteria.
BIO-PROTECT DP provides an invisible barrier to inhibit the growth of bacteria which cause staining and discoloration.
BIO-PROTECT DP provides an invisible barrier to inhibit the growth of fungi (mold and mildew).
BIO-PROTECT DP provides an invisible barrier to inhibit the growth of algae.
BIO-PROTECT DP prevents deterioration caused by bacteria and fungi (mold and mildew).
BIO-PROTECT DP resists development of microbial odors.
BIO-PROTECT DP resists development of stains and discoloration due to bacteria.
BIO-PROTECT DP resists development of stains due to fungi (mold and mildew).
BIO-PROTECT DP resists stains due to algae.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

For Household/residential use packages:

Storage and Disposal: Store in original, tightly-closed container in an area inaccessible to children or persons unfamiliar with its use. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F) and above 0 C (32F). Non-refillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

For Industrial and Commercial Use Packages:
Small Packages (1 gallon or less):
Pesticide Storage: Store in original, tightly-closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Store in original, unopened containers at or below 25 C (77F). This product has a minimum shelf life of 12 months after date of shipment.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Pails, Drums and IBC's (containers greater than one gallon)
Pesticide Storage: Store in original, tightly-closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Store in original, unopened containers at or below 25 C (77F). This product has a minimum shelf life of 12 months after date of shipment.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Containers Handling: REFILLABLE CONTAINER. Refill this container with this product only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill container ¼ full with water. Replace and tighten closure. Tip container in its side and roll it back and forth, ensuring at least one complete revolutions, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty rinsate into application equipment of mix tank or store for later use or disposal. Or pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use of disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING:

Material Sent for Data Extraction

Reg # 71583-5

Description: New Product

☒ Material(s) Sent to Data Extraction Contractors:

- ☒ New Stamped Label Dated 11/3/11
- ☐ Notification Dated _____
- ☐ New CSF(s) Dated _____
- ☐ Other: _____

☒ Decision #: 420075

☐ Other Action/Comments: _____

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Tracy Lantz

Phone: 703-308-8413 Division: AD

Date: 11/7/11

Created February 3, 2011

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:	Date of Issuance:
87583-5	NOV - 3 2011

Term of Issuance: **Unconditional**

Name of Pesticide Product: **Bio-Protect DP**

NOTICE OF PESTICIDE:
x Registration
___ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

PureShield Inc.
1445 Juniper Park, Suite 11
Juniper, FL 33458

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(a) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling change listed below before you release the product for shipment:

   A. Revise the EPA Registration Number to read, "EPA Reg. No. 87583-5"

Signature of Approving Official:

Velma Noble
Product Manager Team-31
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date: NOV - 3 2011

EPA Form 8570-6

7510P
11/3/11

B. Delete the follow statements from the logo at the top of page one. The font used is too small and these statements are repeated elsewhere on the label. Delete: "Distributed by: IDA, 1445 Juniper Park Dr., Suite 11, Juniper, FL 33458" and "A Silicone Quaternary Ammonium Salt".

C. Your product has only been shown to be effective against two public health organisms: *Salmonella choleraesuis* and *Staphylococcus aureus* and thus does not meet the requirements for either a qualified or unqualified "germs" claim. A qualified germs claim is acceptable when the product is shown to be effective against public health related bacteria and one pathogenic fungi or virus. An unqualified germs claim is acceptable when data has been provided which supports effectiveness against public health bacteria, fungi and viruses. (For additional details, see the Agency letter at http://www.epa.gov/oppad001/germs.htm) Delete all references to "germs" from the 1st, 2nd and 4th statements on page 3.

D. Revise the Storage and Disposal statements on page 4 to be in agreement the cited "me-too" label 70871-22 and PR Notice 2007-4 as follows:

1. In the Industrial and Commercial Use Packages section, revised both headings "Storage and Disposal" to read "**Pesticide** Storage."
2. Delete the current language in both Pesticide Disposal statements in the Industrial and Commercial Use Packages section and revise to read as follows: "*Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.*"
3. Provide additional clarity by adding the following statement immediately after "Pails, Drums and IBCs" add: "*(containers greater than one gallon).*"
4. Revise the Container Handling statement in the Pails, Drums and IBCs section by revising to begin as follows: "REFILLABLE CONTAINER. Refill this container with *this product only.* Do not reuse… "
5. Delete the following statements in the Pail, Drums and IBC container handling section beginning: "Fill the container about…" and ending: "…or rinsate collections system." Replace with the following language allowing for two rinsing options: "*Fill container ¼ full with water. Replace and tighten closure. Tip container in its side and roll it back and forth, ensuring at least once complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty rinsate into application equipment of mix tank or store for later use or disposal.*" OR "*Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10*

seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Velma Noble
Product Manager 31
Regulatory Branch I
Antimicrobials Division (7510P)

Enclosure: (Stamped Label, CSPA Germs letter)
7510P:T. Lantz:11/3/11:87583-5

Bio-Protect DP

BIO-PROTECT DP
DISINFECTANT and ANTIMICROBIAL AGENT
A Silicone Quaternary Ammonium Salt

Active Ingredients:	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride	35.60%
	n-alkyl (50% C_{14}, 40% C_{12}, 10% C_{18}) dimethyl benzyl ammonium chloride	6.40%
	Octyl decyl dimethyl ammonium chloride	4.80%
	Didecyl dimethyl ammonium chloride	2.88%
	Dioctyl dimethyl ammonium chloride	1.92%
Other Ingredients:		48.40%
TOTAL INGREDIENTS:		100.00%

Contains over 6% methanol

Reg. No. 87583- **KEEP OUT OF REACH OF CHILDREN** EST – XXXXX-XX-X

DANGER  **POISON**

NET CONTENTS: 2, 4, 8, 16, 20, 22, OR 36 fluid oz.; 1, 5, 55, 150, or 300 gal. Lot No. _____

FIRST AID

Have the product container or label with you when calling the poison control center or doctor, or going for treatment.

IF IN EYES:
- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call poison control center or doctor for treatment advice.

IF INHALED:
- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

IF SWALLOWED:
- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.
- Methanol may cause blindness.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

IF ON SKIN:
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

Manufactured by: PureShield, 1445 Jupiter Park Drive, Suite 11, Jupiter, FL 33458

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER! Corrosive: Methanol may cause blindness. Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing spray mist. Wear protective eyewear (goggles or face shield). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame. De-activation of Bio-Protect DP can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of Bio-Protect DP.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

De-activation may be required during clean up if a spill occurs. De-activation of Bio-Protect DP can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of Bio-Protect DP.

DIRECTIONS FOR USE
For use in homes, offices, and institutions (schools, daycare centers, churches, correctional facilities)

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Allow treated areas and surfaces to dry before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application.

Bio-Protect DP is an effective disinfectant against *Salmonella choleraesuis*, and *Staphylococcus aureus*. Bio-Protect DP is also effective against odor-causing bacteria, bacteria that causes staining and discoloration, fungi (mold and mildew) and algae as a static agent.

Bio-Protect DP may be used for treatment of the following hard non-porous surfaces to impart disinfection (*Salmonella choleraesuis* and *Staphylococcus aureus*), bacteriostatic/fungistatic/algaestatic, and deodorizing activity:

	Pest controlled	Dilution Rate	Method of Application
Tubs, glazed tiles, vanity tops, shower stalls (areas), sinks, washable walls, vinyl wall paper for non-food contact, floors, window sills, cabinets, garbage cans, exterior surfaces of appliances and refrigerators	Odor-causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), *Salmonella choleraesuis* and *Staphylococcus aureus*	0.5 oz/gallon	**SPRAY**: Dilute Bio-Protect DP in water; mix well. Using a trigger pump sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. **For Disinfecting:** Let stand for 10 minutes, then wipe surface dry.

MOLD, MILDEW, ODOR PROTECTOR, ODOR INHIBITOR, AND GERM KILLER

Bio-Protect DP is an antimicrobial agent effective against common household germs and helps prevent the spread of harmful germs on treated hard, non-porous surfaces in kitchen, bathroom, and household.

Bio-Protect DP is an antimicrobial agent effective against microorganisms that cause offensive odors on hard, non-porous surfaces.

Bio-Protect DP is an antimicrobial agent effective against odor-causing bacteria and germs in the kitchen and bathroom.

Bio-Protect DP is an antimicrobial agent effective in controlling mold and mildew, and inhibiting the growth of mold and mildew.

Bio-Protect DP, and antimicrobial agent, disinfects hard, non-porous surfaces and kills *Salmonella choleraesuis* and *Staphylococcus aureus*.

Bio-Protect DP, and antimicrobial agent, can be used in and around bathtubs and shower stalls to prevent the growth of mold and mildew.

Bio-Protect DP provides an invisible barrier to inhibit the growth of odor-causing bacteria.

Bio-Protect DP provides an invisible barrier to inhibit the growth of bacteria which cause staining and discoloration.

Bio-Protect DP provides an invisible barrier to inhibit the growth of fungi (mold and mildew).

Bio-Protect DP provides an invisible barrier to inhibit the growth of algae.

Bio-Protect DP prevents deterioration caused by bacteria and fungi (mold and mildew).

Bio-Protect DP resists development of microbial odors.

Bio-Protect DP resists development of stains and discoloration due to bacteria.

Bio-Protect DP resists development of stains due to fungi (mold and mildew).

Bio-Protect DP resists stains due to algae.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

For Household/residential use packages:

Storage and Disposal: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use.
Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F) and above 0°C (32°F). Non-refillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

For industrial and commercial use packages:

Small Packages (1 gallon or less):
Storage [redacted]. Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F). This product has a minimum shelf life of 12 months after date of shipment.

Pesticide Disposal: [redacted].

Container Handling: Non-refillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Pails, Drums and IBCs:

Storage [redacted]: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F). This product has a minimum shelf life of 12 months after date of shipment.

Pesticide Disposal: [redacted].

Container Handling: REFILLABLE CONTAINER. Refill this container with 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. [redacted]. Repeat this rinsing procedure two more times. Then offer for recycling, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING TO:
PureShield Inc.
1445 Jupiter Park, Suite 11
Jupiter, FL 33458

D 450575
S 897778

presented @ PRIA mtg: 8/4/11

Product: 87583-L Bio-Protect DP

Company: A530 Pureshield

paid $290

Work w Emilia- training

new product is identical to this product → even w revised CSF of 8/10/11 product still identical to 70871-22

additional notes on this products CSF.

Intent: Me too of 70871-22 → 75497-8 (was) → 70871-1S (prior) (CSF included) (Label included)

also citing 70871-18? → 75497-4 → 70871-4 (CSF included)

Source of this product is active registered MUP

Source is [redacted] → this product is Not the same as new product -AI's differ

Issues: ① Doesn't qualify for ~~formulators~~ for one active (need corrected form)

② Did ~~they provide~~ generic data cover? Do they own data? I doubt it

Did not submit any studies ~~required~~ OK - studies not needed

need Chemistry? — required unless same source of AI

need efficacy? — required unless same source of AI

③ Did not include permission letter to cite Inhold Studies

E-label for review ③a (Did not cite a primary eye study)

④ Do they ultimately have the same source of AI - yes as 70871-22 Can they use the efficacy data from the cited product? What is their source?

⑤ Am I sure other products are still currently registered? If no others still registered at this concentration we might have grounds for not allowing danger / skull + crossbones for homeowners

(yes) but for homeowners? (yes) 70871-22

⑥ check data citations [data on 70871-18 (previously 75497-4 and 70871-4) can not support this product.]

OK

they may use data submitted to support 70871-22

8/1/11 emailed 15 day letter to Kevin Kietzel

8/10/11 renegotiation request (30 days) Citing data from 70871-21

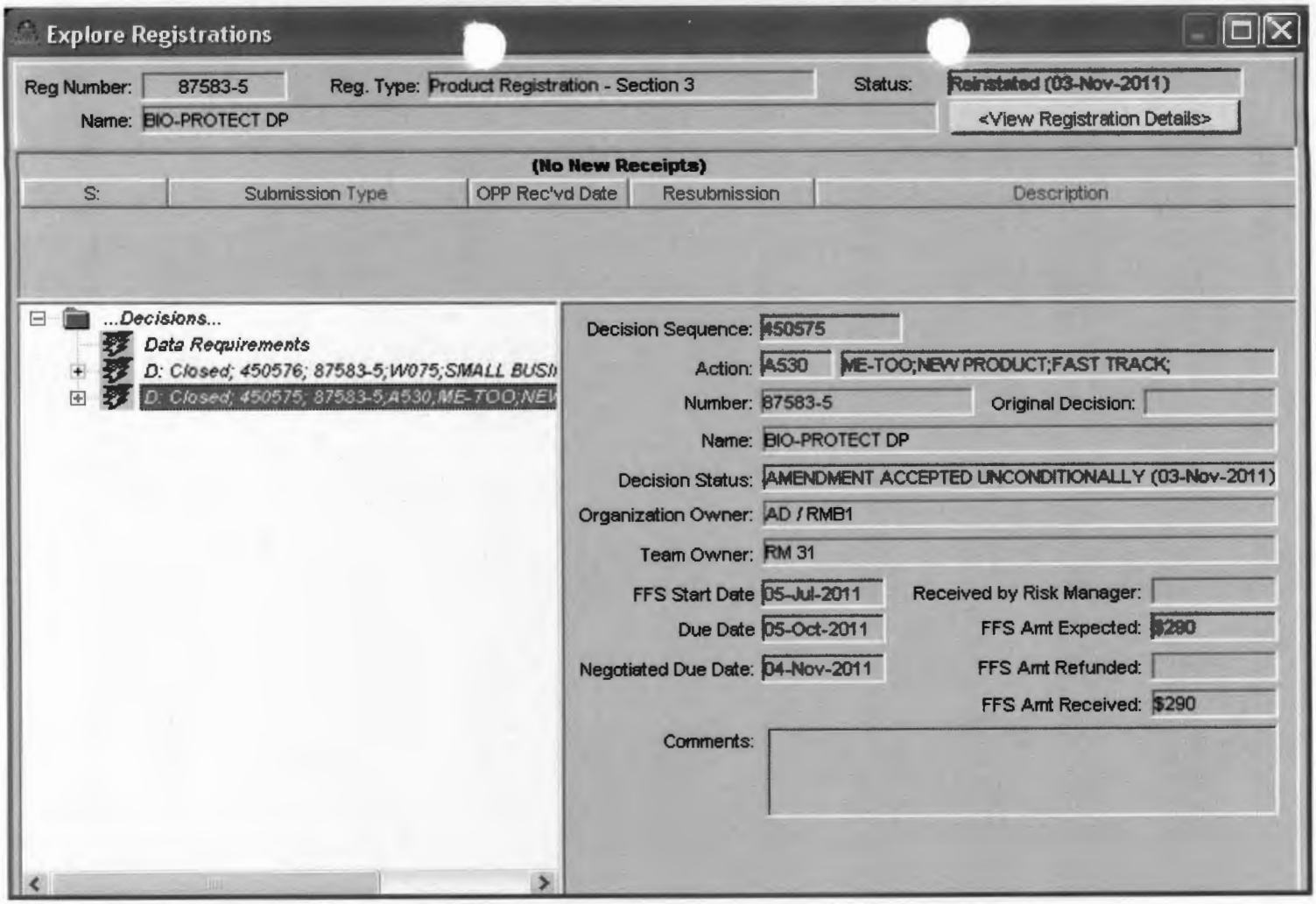
9/28/11 sent renega. + fix attached.

Source is active Reg MUP. I think this is OK

Start 7/5/11 via webforms due 10/5/11

was 70871-21 → 75497-7, was 70871-13

~~11/5/11~~ 11/4/11


Explore Registrations
Reg Number: 87583-5
Reg. Type: Product Registration - Section 3
Status: Reinstated (03-Nov-2011)
Name: BIO-PROTECT DP
<View Registration Details>
(No New Receipts)
S:
Submission Type
OPP Rec'vd Date
Resubmission
Description
...Decisions...
Data Requirements
D: Closed; 450576; 87583-5;W075;SMALL BUSI
D: Closed; 450575; 87583-5;A530;ME-TOO;NEV
Decision Sequence: 450575
Action: A530 ME-TOO;NEW PRODUCT;FAST TRACK;
Number: 87583-5
Original Decision:
Name: BIO-PROTECT DP
Decision Status: AMENDMENT ACCEPTED UNCONDITIONALLY (03-Nov-2011)
Organization Owner: AD / RMB1
Team Owner: RM 31
FFS Start Date 05-Jul-2011
Received by Risk Manager:
Due Date 05-Oct-2011
FFS Amt Expected: $290
Negotiated Due Date: 04-Nov-2011
FFS Amt Refunded:
FFS Amt Received: $290
Comments:

http://www.epa.gov/oppad001/germs.htm
Last updated on Thursday, May 12, 2011

Pesticides: Regulating Pesticides

Consumer Speciality Products Association (CSPA) "Germs" Letter

January 5, 2005

Ms. Brigid D. Klein
Consumer Specialty Products Association
900 17th Street, NW
Washington, DC 20006

Dear Ms. Klein:

CSPA has requested that EPA clarify a March 26, 2004 letter that provides guidance on the use of the term "germs" on antimicrobial labels. Specifically, CSPA requested that the Agency point out in its guidance that the use of the term "germs"on sanitizer products will be addressed at a later time. As a result of making this change, this revised letter will supersede my letter of March 26, 2004.

By way of background, CSPA in a letter dated December 17, 2003 asked the Agency to provide guidance on when the term "germs" can be used on an antimicrobial label. The use of the "germs" term over time has come to be commonly associated with disease causing organisms, including ones caused by bacteria, viruses or fungi. As a result, the Agency considers the term "germs" to be a public health claim which must be supported by appropriate efficacy data. As we have previously discussed, due to the common association of this term with disease bearing organisms, the Agency does not believe that the term can be used as a non-public health claim or on a non-public health product, even if qualified.

The Agency believes the use of the term "germs"must be limited to products which meet certain specified criteria. Further, as previously stated, EPA considers a germ claim to be a broad term that encompasses bacteria, viruses and/or fungi. Those products containing a disinfectant claim including viruses and/or fungi, in addition to a sanitizer claim, may use germ claims. The criteria for obtaining germ claims on disinfecting products is described in more detail below. This guidance is for products that are disinfectants. As previously stated, guidance for sanitizer only products will be addressed at a later time.

Note, in order to use the term "germs" on an antimicrobial label, the product must bear directions for use as a disinfectant. If you remove the disinfectant directions from the label, then you must also remove the term "germs" from the label.

Criteria For A Germs Claim

1. In order to make a qualified "germ" claim on a product label, a product must be registered as a general purpose/broad spectrum disinfectant product with additional label claims against one of the two classes of organisms listed below:

- Fungi - One pathogenic fungi (usually Trichophyton mentagrophytes) that is representative of the use sites listed for the product.
- Viruses - One enveloped and/or non-enveloped virus that is representative of the use sites listed for

the product.
- All studies to support disinfectant, fungicidal, and virucidal claims must be conducted according to EPA guidelines.
- The front panel of the label for a qualified public health "germ" claim must contain a designator that refers the user to the qualified statements. A qualified statement is one that clearly describes the type of "germ" the product is efficacious against. When the word "germ" is used on the front panel of a label, an asterisk is required to indicate that there is clarifying language elsewhere on the label.

  Examples: Front panel - Kills germs*
  Back panel - Kills Salmonella choleraesuis and Staphylococcus aureus
  and (list virus or fungi)

2. In order to make an unqualified "germ" claim on a label, a product must have public health data developed using current EPA guidelines for all three of the major classes of organisms:

- Bacteria - meet the general purpose/broad spectrum disinfectant performance standard per EPA guidelines.
- Fungi - One pathogenic fungi (usually Trichopyton mentagrophytes) that is representative of the use sites listed for the product. Studies to be conducted according to EPA guidelines.
- Viruses - One enveloped and non-enveloped virus that is representative of the use sites for the product. Studies to be conducted according to EPA guidelines.
- The claim "germs" can be used without descriptors of the type of organism. No asterisk is required. The claim can appear on the front or back/side panel of a label. However, specific organisms must still be listed on the label.

  Examples: Kills Germs
  Kills germs in the bathroom and/or kitchen

- Qualified statements are optional and can be added to the product label, if desired.

The Agency intends to implement this guidance immediately. New registration applications will be reviewed using this guidance. The Agency will also apply this guidance when conducting label review of currently registered products. In addition, this guidance will also be used when the Agency conducts label reviews for product specific reregistration.

Sincerely,

Frank T. Sanders, Director
Antimicrobials Division (7510C)

Fee for Service

{897778r~

This package includes the following

- (•) New Registration
- ( ) Amendment

☐ Studies? ☑ Fee Waiver?

☐ volpay % Reduction: 75

for Division

- (•) AD
- ( ) BPPD
- ( ) RD

Risk Mgr. 31

Receipt No. S- 897778

EPA File Symbol/Reg. No. 87583-L

Pin-Punch Date: 6/14/2011

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A530

Granted: A530

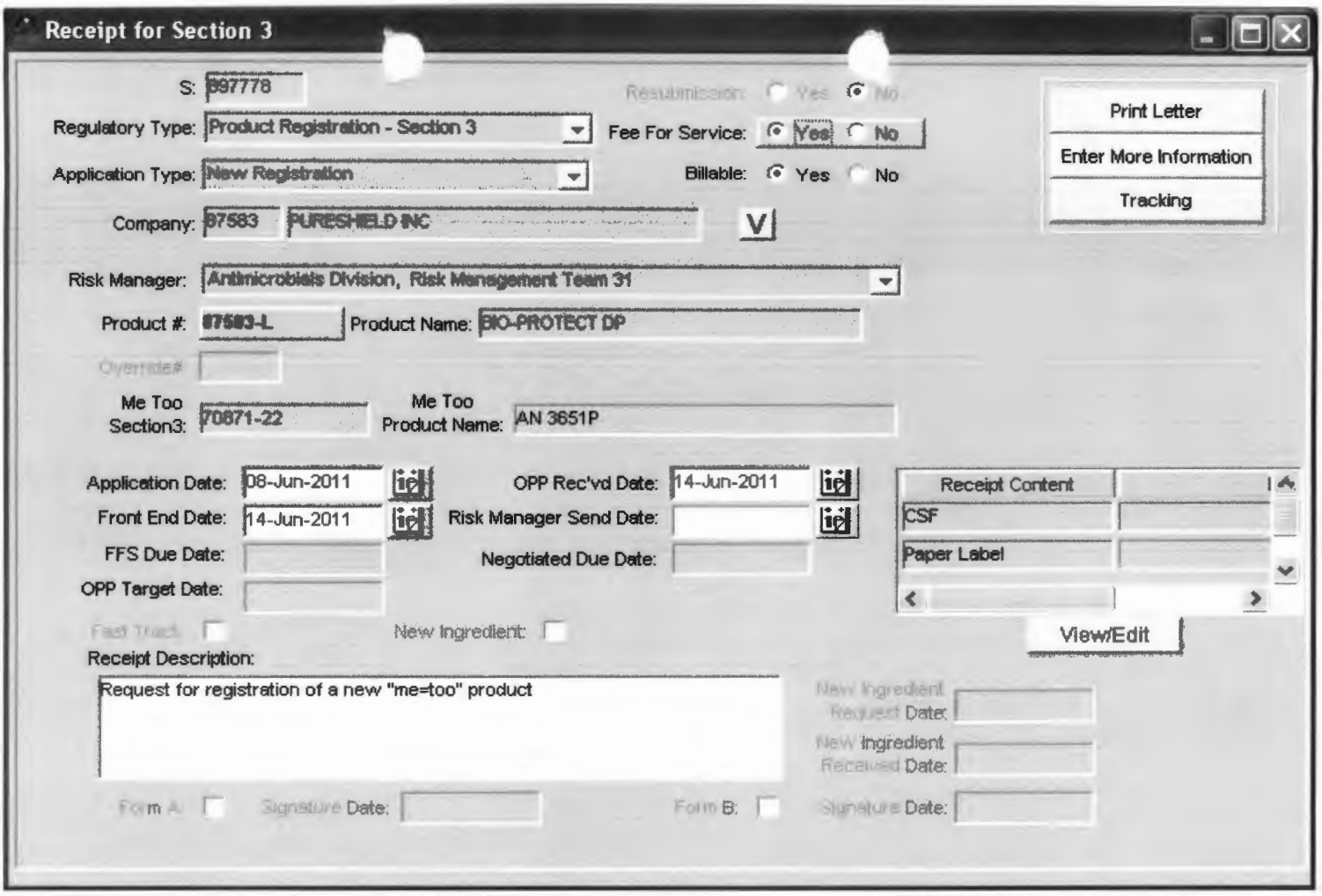
Amount Due: $ 1103

Parent/Child Decisions:

☑ Inert Cleared for Intended Use ☑ Uncleared Inert in Product

Reviewer: Team 2 Date: 6/15/11

Remarks:


Receipt for Section 3
S: 597778
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Company: 87583 PURESHIELD INC
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 31
Product #: 87583-L
Product Name: BIO-PROTECT DP
Override#
Me Too Section3: 70871-22
Me Too Product Name: AN 3651P
Application Date: 08-Jun-2011
OPP Rec'vd Date: 14-Jun-2011
Front End Date: 14-Jun-2011
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
CSF
Paper Label
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Request for registration of a new "me=too" product
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

RE: Reg No. 87583-L OPP Decision D 450575

Kevin Kutcel to Tracy Lantz 11/03/2011 09:17 PM

"Kevin Kutcel" <kevinkutcel@gmail.com>
Tracy Lantz/DC/USEPA/US@EPA

Tracy,

Here is the complete label for Reg No 87583-L.

Kevin

-----Original Message-----
From: Lantz.Tracy@epamail.epa.gov [mailto:Lantz.Tracy@epamail.epa.gov]
Sent: Thursday, November 03, 2011 8:09 PM
To: Kevin Kutcel
Subject: RE: Reg No. 87583-L OPP Decision D 450575

Would you please send me the entire label (including the revised page one) in electronic format?
Thanks

Bio-Protect DP

BIO-PROTECT DP
DISINFECTANT and ANTIMICROBIAL AGENT
A Silicone Quaternary Ammonium Salt

Active Ingredients:	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride	35.60%
	n-alkyl (50% C_{14}, 40% C_{12}, 10% C_{18}) dimethyl benzyl ammonium chloride	6.40%
	Octyl decyl dimethyl ammonium chloride	4.80%
	Didecyl dimethyl ammonium chloride	2.88%
	Dioctyl dimethyl ammonium chloride	1.92%
Other Ingredients:		48.40%
TOTAL INGREDIENTS:		100.00%

Contains over 6% methanol

Reg. No. 87583- **KEEP OUT OF REACH OF CHILDREN** EST – XXXXX-XX-X

DANGER  **POISON**

NET CONTENTS: 2, 4, 8, 16, 20, 22, OR 36 fluid oz.; 1, 5, 55, 150, or 300 gal. Lot No. _____

FIRST AID

Have the product container or label with you when calling the poison control center or doctor, or going for treatment.

IF IN EYES:
- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call poison control center or doctor for treatment advice.

IF INHALED:
- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

IF SWALLOWED:
- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.
- Methanol may cause blindness.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

IF ON SKIN:
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

Manufactured by: PureShield, 1445 Jupiter Park Drive, Suite 11, Jupiter, FL 33458

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER! Corrosive: Methanol may cause blindness. Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing spray mist. Wear protective eyewear (goggles or face shield). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame. De-activation of Bio-Protect DP can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of Bio-Protect DP.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

De-activation may be required during clean up if a spill occurs. De-activation of Bio-Protect DP can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of Bio-Protect DP.

DIRECTIONS FOR USE
For use in homes, offices, and institutions (schools, daycare centers, churches, correctional facilities)

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Allow treated areas and surfaces to dry before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application.

Bio-Protect DP is an effective disinfectant against *Salmonella choleraesuis*, and *Staphylococcus aureus*. Bio-Protect DP is also effective against odor-causing bacteria, bacteria that causes staining and discoloration, fungi (mold and mildew) and algae as a static agent.

Bio-Protect DP may be used for treatment of the following hard non-porous surfaces to impart disinfection (*Salmonella choleraesuis* and *Staphylococcus aureus*), bacteriostatic/fungistatic/algaestatic, and deodorizing activity:

	Pest controlled	Dilution Rate	Method of Application
Tubs, glazed tiles, vanity tops, shower stalls (areas), sinks, washable walls, vinyl wall paper for non-food contact, floors, window sills, cabinets, garbage cans, exterior surfaces of appliances and refrigerators	Odor-causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), *Salmonella choleraesuis* and *Staphylococcus aureus*	0.5 oz/gallon	**SPRAY**: Dilute Bio-Protect DP in water; mix well. Using a trigger pump sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. **For Disinfecting:** Let stand for 10 minutes, then wipe surface dry.

MOLD, MILDEW, ODOR PROTECTOR, ODOR INHIBITOR, AND GERM KILLER

Bio-Protect DP is an antimicrobial agent effective against common household germs and helps prevent the spread of harmful germs on treated hard, non-porous surfaces in kitchen, bathroom, and household.

Bio-Protect DP is an antimicrobial agent effective against microorganisms that cause offensive odors on hard, non-porous surfaces.

Bio-Protect DP is an antimicrobial agent effective against odor-causing bacteria and germs in the kitchen and bathroom.

Bio-Protect DP is an antimicrobial agent effective in controlling mold and mildew, and inhibiting the growth of mold and mildew.

Bio-Protect DP, and antimicrobial agent, disinfects hard, non-porous surfaces and kills *Salmonella choleraesuis* and *Staphylococcus aureus*.

Bio-Protect DP, and antimicrobial agent, can be used in and around bathtubs and shower stalls to prevent the growth of mold and mildew.

Bio-Protect DP provides an invisible barrier to inhibit the growth of odor-causing bacteria.

Bio-Protect DP provides an invisible barrier to inhibit the growth of bacteria which cause staining and discoloration.

Bio-Protect DP provides an invisible barrier to inhibit the growth of fungi (mold and mildew).

Bio-Protect DP provides an invisible barrier to inhibit the growth of algae.

Bio-Protect DP prevents deterioration caused by bacteria and fungi (mold and mildew).

Bio-Protect DP resists development of microbial odors.

Bio-Protect DP resists development of stains and discoloration due to bacteria.

Bio-Protect DP resists development of stains due to fungi (mold and mildew).

Bio-Protect DP resists stains due to algae.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

For Household/residential use packages:

Storage and Disposal: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use.
Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F) and above 0°C (32°F). Non-refillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

For industrial and commercial use packages:

Small Packages (1 gallon or less):
Storage and Disposal: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F). This product has a minimum shelf life of 12 months after date of shipment.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: Non-refillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Pails, Drums and IBCs:

Storage and Disposal: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F). This product has a minimum shelf life of 12 months after date of shipment.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: REFILLABLE CONTAINER. Refill this container with 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING TO:
PureShield Inc.
1445 Jupiter Park, Suite 11
Jupiter, FL 33458

Reg. No. 87583-L
Kevin Kutcel
to:
Tracy Lantz
11/03/2011 09:49 AM
Hide Details
From: "Kevin Kutcel"

To: Tracy Lantz/DC/USEPA/US@EPA

Dear Tracy,

In response to your e-mail dated 11/2/2011 pertaining to Reg. No. 87583-L, [redacted]. Also, please accept the first page of the label in which the changes you requested have been made. The PureShield address is on the bottom of the page. Please advise if any further information is required.

Warm Regards,

Kevin Kutcel
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
Fax: 440-398-0476
E-mail: kevinkutcel@gmail.com

Product ingredient source information may be entitled to confidential treatment

[redacted] Reg No. 87583-L

Tracy Lantz to Kevin Kutcel 11/02/2011 11:42 PM
cc Velma Noble, Dennis Edwards

From: Tracy Lantz/DC/USEPA/US
To: "Kevin Kutcel" <kevinkutcel@gmail.com>
Cc: Velma Noble DC USEPA/US@EPA, Dennis Edwards DC USEPA US@EPA

Thank you very much for your extremely quick reply to my e-mail message. I sincerely appreciate it.

[redacted]

In addition, if possible, would you please make a few more corrections to the first page of your label?
1) The word poison should appear in red ink on a contrasting background
2) Move the "methanol may cause blindness" statement into the "If Swallowed" section.
3) Revise the following two statements such that each in listed in a font size which is similar or the same as the font used in the first aid statements: "Distributed by: IDA 1445 Juniper Park Dr., Suite 11, Juniper FL 33458" and "A Silicone Quaternary Ammonium Salt"

Again, if possible, please reply by 1:30 PM on Thursday.

Thanks very much.

"Kevin Kutcel" Tracy, Per your request below pertaining to Reg.... 11/02/2011 09:04:06 PM

From: "Kevin Kutcel" <kevinkutcel@gmail.com>
To: Tracy Lantz/DC/USEPA/US@EPA
Cc: Velma Noble/DC/USEPA/US@EPA
Date: 11/02/2011 09:04 PM
Subject: RE: Reg No. 87583-L OPP Decision D 450575

Tracy,

Per your request below pertaining to Reg. No. 87583-L, please accept the attachment with the following documents:

1. Inhold permission letter with signature showing on bottom of page.

2. Revised CSF with the upper and lower limits for [redacted] corrected to be [redacted] respectively.

3. Revised data matrix with the "Cite-All" replaced with "See Permission Letter."

Please advise if any further information is required. I greatly appreciate your e-mail allowing me to respond to these deficiencies.

Warm Regards,

Kevin Kutcel
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
Fax: 440-398-0476
E-mail: kevinkutcel@gmail.com

-----Original Message-----
From: Lantz.Tracy@epamail.epa.gov [mailto:Lantz.Tracy@epamail.epa.gov]
Sent: Wednesday, November 02, 2011 8:31 PM
To: Kevin Kutcel
Cc: Noble.Velma@epamail.epa.gov
Subject: Re: Reg No. 87583-L OPP Decision D 450575

I am in the final steps of reviewing your application. In reviewing the forms in the attached pdf, I have found several items which must be corrected.

1) Inhold permission letter: I am unable to read the signature at the bottom and it seems that the typed name of the signer has been cut off from the image. Please send a "cleaner" copy in which the signature can be read and the typed name of the signer is included.

2) Revised page one of the product specific data matrix: This form looks fine except for the column titled "note". Here you have indicated "cite-all". Since you have indicated that you are citing Inhold data and that you have been given permission to do so, delete the incorrect phrase "cite-all" and replace with "see permission letter." You are not using the cite all option.

3) The submitted CSF included limits for [redacted] that are not in agreement with the certified limits as specified by 40 CFR. The upper and lower limits for [redacted] may be + or - [redacted] Please revise to indicate the upper limit of [redacted] and the lower limit of [redacted] When revising the CSF please retain the date of 8/10/11.

Please correct these forms, scan, and e-mail to me as a pdf.

If at all possible, please send to me Thursday by 1 PM so that I can finalize the decision for this application.

Thanks

Tracy

From: "Kevin Kutcel" <kevinkutcel@gmail.com>
To: Tracy Lantz/DC/USEPA/US@EPA
Date: 08/10/2011 03:24 PM
Subject: Reg No. 87583-L OPP Decision D 450575

Product ingredient source information may be entitled to confidential treatment

Dear Ms. Lantz,

Per our conversation and in response to OPP Decision Number D 450575, please accept the attachment that I believe resolves the deficiencies outlined in your letter and what we discussed. The attachment includes the following signed documentation:

1. [redacted]

2. [redacted]

3. Revised page 1 of 2 of the Data Matrix (Form 8570-35) in which the citation for MRID 45121306 has been corrected to state, "Kuhn, J. (1999) AM3651P: Primary Eye Irritation Study in Rabbits. Lab Report 4854-98. 13 p."

4. Letter of authorization from Inhold LLC to cite the data on file with the EPA supporting the "Me-Too" product Reg. No. 70871-22.

I believe this attached documentation fulfills the deficiencies outlined in your letter dated August 2, 2011. Therefore, I would respectfully request that the revised negotiated PRIA date only be extended 30 days beyond the current due date of October 5, 2011.

Please advise if you should have any further issues or questions concerning this application.

Warm Regards,

Kevin Kutcel
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
Fax: 440-398-0476
E-mail: kevinkutcel@gmail.com

(See attached file: EPA Response Decision D450575 8'10'110001.pdf)

87583-L 11'2'110001.pdf

Re: Reg No. 87583-L OPP Decision D 450575
Tracy Lantz to Kevin Kutcel
Velma Noble
11/02/2011 08:31 PM

Tracy Lantz/DC/USEPA/US
"Kevin Kutcel" <kevinkutcel@gmail.com>
Velma Noble/DC/USEPA/US@EPA

I am in the final steps of reviewing your application. In reviewing the forms in the attached pdf, I have found several items which must be corrected.

1) Inhold permission letter: I am unable to read the signature at the bottom and it seems that the typed name of the signer has been cut off from the image. Please send a "cleaner" copy in which the signature can be read and the typed name of the signer is included.

2) Revised page one of the product specific data matrix: This form looks fine except for the column titled "note". Here you have indicated "cite-all". Since you have indicated that you are citing Inhold data and that you have been given permission to do so, delete the incorrect phrase "cite-all" and replace with "see permission letter." You are not using the cite all option.

3) The submitted CSF included limits for [redacted] that are not in agreement with the certified limits as specified by 40 CFR. The upper and lower limits for [redacted] may be + or - [redacted] Please revise to indicate the upper limit of [redacted] and the lower limit of [redacted] When revising the CSF please retain the date of 8/10/11.

Please correct these forms, scan, and e-mail to me as a pdf.

If at all possible, please send to me Thursday by 1 PM so that I can finalize the decision for this application.

Thanks

Tracy

"Kevin Kutcel" Dear Ms. Lantz, 08/10/2011 03:24:45 PM

From: "Kevin Kutcel" <kevinkutcel@gmail.com>
To: Tracy Lantz/DC/USEPA/US@EPA
Date: 08/10/2011 03:24 PM
Subject: Reg No. 87583-L OPP Decision D 450575

Dear Ms. Lantz,

Per our conversation and in response to OPP Decision Number D 450575, please accept the attachment that I believe resolves the deficiencies outlined in your letter and what we discussed. The attachment includes the following signed documentation:

1. [redacted]

[redacted].
2. [redacted]
3. Revised page 1 of 2 of the Data Matrix (Form 8570-35) in which the citation for MRID 45121306 has been corrected to state, "Kuhn, J. (1999) AM3651P: Primary Eye Irritation Study in Rabbits. Lab Report 4854-98. 13 p."
4. Letter of authorization from Inhold LLC to cite the data on file with the EPA supporting the "Me-Too" product Reg. No. 70871-22.

I believe this attached documentation fulfills the deficiencies outlined in your letter dated August 2, 2011. Therefore, I would respectfully request that the revised negotiated PRIA date only be extended 30 days beyond the current due date of October 5, 2011.

Please advise if you should have any further issues or questions concerning this application.

Warm Regards,

Kevin Kutcel
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
Fax: 440-398-0476
E-mail: kevinkutcel@gmail.com

EPA Response Decision D450575 8'10'110001.pdf

Product ingredient source information may be entitled to confidential treatment

RE: Reg No. 87583-L OPP Decision D 450575

Kevin Kutcel to Tracy Lantz 10/31/2011 09:49 AM

From: "Kevin Kutcel" <kevinkutcel@gmail.com>
To: Tracy Lantz/DC/USEPA/US@EPA

Dear Ms. Lantz,

Per your request, please find the attached page 1 for the label corresponding to File Symbol 87583-L with the change of the active to read trimethoxysilyl. Thank you for allowing me to make this correction.

Warm Regards,

Kevin Kutcel
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
Fax: 440-398-0476
E-mail: kevinkutcel@gmail.com

-----Original Message-----
From: Lantz.Tracy@epamail.epa.gov [mailto:Lantz.Tracy@epamail.epa.gov]
Sent: Friday, October 28, 2011 4:25 PM
To: Kevin Kutcel
Subject: Re: Reg No. 87583-L OPP Decision D 450575

Please provide me with another correction for this submission. The name of the active ingredient, PC code 107401, should be corrected to read trimethoxysilyl. I believe it is correct on all the forms except for the first page of the label. Please send me a corrected first page of the label via e-mail. I will be in touch with you early next week if any other corrections are needed.

Thanks for your assistance.
(Embedded image moved to file: pic07239.jpg)

From: "Kevin Kutcel" <kevinkutcel@gmail.com>
To: Tracy Lantz/DC/USEPA/US@EPA
Date: 08/10/2011 03:24 PM
Subject: Reg No. 87583-L OPP Decision D 450575

Dear Ms. Lantz,

Per our conversation and in response to OPP Decision Number D 450575, please accept the attachment that I believe resolves the deficiencies outlined in your letter and what we discussed. The attachment includes the following signed documentation:

Product ingredient source information may be entitled to confidential treatment

1. [redacted]

2. [redacted]

3. Revised page 1 of 2 of the Data Matrix (Form 8570-35) in which the citation for MRID 45121306 has been corrected to state, "Kuhn, J. (1999) AM3651P: Primary Eye Irritation Study in Rabbits. Lab Report 4854-98. 13 p."

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Please advise if you should have any further issues or questions concerning this application.

Warm Regards,

Kevin Kutcel
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
Fax: 440-398-0476
E-mail: kevinkutcel@gmail.com

(See attached file: EPA Response Decision D450575 8'10'110001.pdf)

Reg No. 87583-L OPP Decision D 450575
Kevin Kutcel
to:
Tracy Lantz
08/10/2011 03:24 PM
Hide Details
From: "Kevin Kutcel" <kevinkutcel@gmail.com>

To: Tracy Lantz/DC/USEPA/US@EPA

Corrected revised forms attached

1 Attachment

EPA Response Decision D450575 8'10'110001.pdf

Dear Ms. Lantz,

Per our conversation and in response to OPP Decision Number D 450575, please accept the attachment that I believe resolves the deficiencies outlined in your letter and what we discussed. The attachment includes the following signed documentation:

1. [redacted]
2. [redacted]
3. Revised page 1 of 2 of the Data Matrix (Form 8570-35) in which the citation for MRID 45121306 has been corrected to state, "Kuhn, J. (1999) AM3651P: Primary Eye Irritation Study in Rabbits. Lab Report 4854-98. 13 p."
4. Letter of authorization from Inhold LLC to cite the data on file with the EPA supporting the "Me-Too" product Reg. No. 70871-22.

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Product ingredient source information may be entitled to confidential treatment

Therefore, I would respectfully request that the revised negotiated PRIA date only be extended 30 days beyond the current due date of October 5, 2011.

Please advise if you should have any further issues or questions concerning this application.

Warm Regards,

Kevin Kutcel
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
Fax: 440-398-0476
E-mail: kevinkutcel@gmail.com

Recommendation of Division Directors
Negotiated Due Dates

Decision #: D450575	Registration #: 87583-L	Petition #:

☑ *See page 2 for additional registration entries*

Chemical Name: 3-trihydroxsilyl propyldimethyloctadecyl ammonium chloride, 50% C14, 40% C12, 10% C18 dimethyl benzyl ammon

Fee Category: A530	**PRIA Decision Time Frame:** 90 days	
Submitted by: Tracy Lantz	**Branch:** OCSPP/OPP/AD	**Date:** 09/28/2011

Company: PureShield Inc.

Original PRIA Due Date: 10/05/2011	**Proposed New PRIA Due Date:** 11/04/2011

Previous Negotiated Due Dates:

Is the "Fix" in-house? ☑ Yes ☐ No ☐ n/a	**If not, date "Fix" expected:**

Negotiated Due Date Reason:

Additional Data Required	☐ Product Chemistry	☐ Toxicology	☐ Acute Tox	☐ Environmental	
	☐ Efficacy	☐ Ecological	☐ Residue	☐ Other	
Data Deficiencies	☐ Product Chemistry	☑ Acute Tox	☐ Efficacy	☐ Residue	☐ Toxicology
	☐ Environmental	☐ Ecological	☐ Labeling	☐ Other	☐ Not Submitted
Late Risk Assessment	☐ Human Health	☐ Ecological			
Interim Consideration	☐ Agency Initiated	☐ Registrant Initiated			

☐ CSF	☐ Public Process	☐ Risk Issues Environmental	☐ Risk Issues Human Health
☐ Impurities Review	☐ Label	☐ Administrative-FR Notice	☐ Other – Comment Field

Summary of Deficiency Type(s): ☑ **Not Submitted (N)** ☐ **Deficiencies (D)**

Product Chemistry: ☐ **Acute Tox:** ☑ **Efficacy:** ☐ **Labeling:** ☐ **Ecological Data:** ☐ **Other (describe):** ☑

see page two

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

see page two

"75 Day" Letter sent? ☑ **Yes, Date sent** 08/02/2011 ☐ **No and reason for none?** *Add comments on page 2*

Rationale for Proposed Due Date: Allow Agency time to review new data compensation/data requirements

Registrant notified that this is the last negotiation? ☐ **Yes** ☑ **Not Applicable**

Approve: ☑	**Disapprove:** ☐

If disapproved, action to be taken:

OD or DOD Signature: *CN=Marty Monell/OU=DC/O=USEPA/C=US*	**Date:** *09/29/2011*

Decision #:	Registration #:	Petition #:

Issue(s) (describe in detail):

Summary of Deficiencies:

Submitted Formulator's Exemption statement is not in agreement with CSF, generic data compensation for active ingredient has not been provided, product specific data is incomplete.

Describe Interactions with Company:

Letter describing deficienies was sent via e-mail on 8/1/11 and via USP on 8/2/11. Consultant replied via e-mail with fix and renegotiation request on 8/10/11.

Comment(s):

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv4a.pdf
Form Number: PRIA
Document Identifier: PRIA-11271093044-TL

SUBMITTED on 09/28/2011 at 10:03:50 AM by CN=Tracy Lantz/OU=DC/O=USEPA/C=US

APPROVED on 09/29/2011 at 09:11:32 AM by CN=Dennis Edwards/OU=DC/O=USEPA/C=US

APPROVED on 09/29/2011 at 10:32:06 AM by CN=Joan Harrigan-Farrelly/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 09/29/2011 at 10:49:08 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US

Recommendation of Division Directors
Negotiated Due Dates

Decision #: D450575	**Registration #:** 87583-L	**Petition #:**

☑ *See page 2 for additional registration entries*

Chemical Name: 3-trihydroxsilyl propyldimethyloctadecyl ammonium chloride, 50% C14, 40% C12, 10% C18 dimethyl benzyl ammon

Fee Category: A530		**PRIA Decision Time Frame:** 90 days	
Submitted by: Tracy	Lantz	**Branch:** OCSPP/OPP/AD	**Date:** 09/28/2011

Company: PureShield Inc.

Original PRIA Due Date: 10/05/2011	**Proposed New PRIA Due Date:** 11/04/2011

Previous Negotiated Due Dates:

Is the "Fix" in-house? ☑ Yes ☐ No ☐ n/a	**If not, date "Fix" expected:**

Negotiated Due Date Reason:

Additional Data Required	☐ Product Chemistry	☐ Toxicology	☐ Acute Tox	☐ Environmental	
	☐ Efficacy	☐ Ecological	☐ Residue	☐ Other	
Data Deficiencies	☐ Product Chemistry	☑ Acute Tox	☐ Efficacy	☐ Residue	☐ Toxicology
	☐ Environmental	☐ Ecological	☐ Labeling	☐ Other	☐ Not Submitted
Late Risk Assessment	☐ Human Health	☐ Ecological			
Interim Consideration	☐ Agency Initiated	☐ Registrant Initiated			

☐ CSF	☐ Public Process	☐ Risk Issues Environmental	☐ Risk Issues Human Health
☐ Impurities Review	☐ Label	☐ Administrative-FR Notice	☐ Other – Comment Field

Summary of Deficiency Type(s): ☑ **Not Submitted (N)** ☐ **Deficiencies (D)**

Product Chemistry: ☐ **Acute Tox:** ☑ **Efficacy:** ☐ **Labeling:** ☐ **Ecological Data:** ☐ **Other (describe):** ☑

see page two

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

see page two

"75 Day" Letter sent? ☑ **Yes, Date sent** 08/02/2011 ☐ **No and reason for none?** *Add comments on page 2*

Rationale for Proposed Due Date: Allow Agency time to review new data compensation/data requirements

Registrant notified that this is the last negotiation? ☐ **Yes** ☑ **Not Applicable**

Approve: ☐	**Disapprove:** ☐

If disapproved, action to be taken:

OD or DOD Signature:	**Date:**

Decision #:	Registration #:	Petition #:

Issue(s) (describe in detail):

Summary of Deficiencies:

Submitted Formulator's Exemption statement is not in agreement with CSF, generic data compensation for active ingredient has not been provided, product specific data is incomplete.

Describe Interactions with Company:

Letter describing deficienies was sent via e-mail on 8/1/11 and via USP on 8/2/11. Consultant replied via e-mail with fix and renegotiation request on 8/10/11.

Comment(s):

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv4a.pdf
Form Number: PRIA
Document Identifier: PRIA-11271093044-TL

SUBMITTED on 09/28/2011 at 10:03:50 AM by CN=Tracy Lantz/OU=DC/O=USEPA/C=US

Reg No. 87583-L OPP Decision D 450575
Kevin Kutcel
to:
Tracy Lantz
08/10/2011 03:24 PM
Hide Details
From: "Kevin Kutcel" <kevinkutcel@gmail.com>

To: Tracy Lantz/DC/USEPA/US@EPA

1 Attachment

EPA Response Decision D450575 8'10'110001.pdf

Dear Ms. Lantz,

Per our conversation and in response to OPP Decision Number D 450575, please accept the attachment that I believe resolves the deficiencies outlined in your letter and what we discussed. The attachment includes the following signed documentation:

1. [redacted]
2. [redacted]
3. Revised page 1 of 2 of the Data Matrix (Form 8570-35) in which the citation for MRID 45121306 has been corrected to state, "Kuhn, J. (1999) AM3651P: Primary Eye Irritation Study in Rabbits. Lab Report 4854-98. 13 p."
4. Letter of authorization from Inhold LLC to cite the data on file with the EPA supporting the "Me-Too" product Reg. No. 70871-22.

I believe this attached documentation fulfills the deficiencies outlined in your letter dated August 2, 2011.

Therefore, I would respectfully request that the revised negotiated PRIA date only be extended 30 days beyond the current due date of October 5, 2011.

Please advise if you should have any further issues or questions concerning this application.

Warm Regards,

Kevin Kutcel
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
Fax: 440-398-0476
E-mail: kevinkutcel@gmail.com

OPP Decision Number D 450575

Kevin R. Kutcel
Agent for PureShield Inc.
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256

AUG - 2 2011

Subject: Application for Registration
Product Name: Bio-Protect DP
EPA Reg. No.: 87583-L
Application Date: June 8, 2011
EPA Receipt Date: June 14, 2011

Dear Mr. Kutcel:

Our records indicate that the decision review period for EPA to make a determination regarding the above referenced application ends on October 5, 2011 as pursuant to the Pesticide Registration Improvement Act (PRIA). The application has been determined, pursuant to 40 CFR 152.105, not to be sufficiently complete to process; therefore, the application is considered deficient. Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it.

CONCURRENCES								
SYMBOL	7510P							
SURNAME	J. Fort							
DATE	8/1/11							

Address the following deficiencies:

Formulator's Exemption Statement

The submitted Formulator's Exemption Statement is not acceptable. [redacted]

Generic Data Compensation

[redacted]. Should you desire to use the cite all option for any data requirement, also include a list of the data submitters for 3-(trimethyloxysilyl) propyldimethyl octadecyl ammonium chloride.

Product Specific Data

1) You have indicated that you have a permission letter from Inhold allowing you to cite their data. Such a letter has not been found in the file for this product. Please submit this letter.

2) In addition, you have not provided a citation to support the requirement for a primary eye irritation study. Submit a revised product specific data matrix which includes a citation/method of support for this study.

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on October 5, 2011. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. Establish a new due date. You may resolve the issues identified in this letter by submitting a reply to the Agency by August 10, 2011 with information as how you plan to address these deficiencies. Please include your proposed re-negotiated PRIA due date and the date you expect to submit the fix at this time. Your re-negotiated PRIA due date must include the date that you expect to submit the fix plus an additional 30 days beyond the current due date of October 5, 2011 for Agency review. If no other issues arise as a result of your response to this letter or during our review process, and the information is found to be acceptable, it is the Agency's expectation that resolution of the deficiencies will result in the granting of your application.

2. **Withdraw the application.** Alternatively, you may notify us not later than August 10, 2011 that you are withdrawing your application. As noted above, withdrawal concludes the Agency's review of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee.

3. **Not respond.** If the Agency does not hear from you by August 10, 2011 the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by **August 10, 2011** by contacting Tracy Lantz by telephone, (703) 308-6415, or by e-mail at Lantz.tracy@epa.gov or Velma Noble by telephone at (703) 308-6233 or by e-mail at Noble.velma@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Tracy Lantz

for Velma Noble
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)

7510P: T.Lantz:8/1/11:87583-L less than 75 day letter

	CONCURRENCES							
SYMBOL								
SURNAME								
DATE								

Deficiency letter for 87583-L
Tracy Lantz to: Kevin Kutcel
Cc: Velma Noble, Emilia Oiguenblik

08/01/2011 05:47 PM

You will receive a hard copy of this letter in the mail shortly.
Please reply by August 10, 2011

OPP Decision Number D 450575

Kevin R. Kutcel
Agent for PureShield Inc.
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256

Subject: Application for Registration
Product Name: Bio-Protect DP
EPA Reg. No.: 87583-L
Application Date: June 8, 2011
EPA Receipt Date: June 14, 2011

Dear Mr. Kutcel:

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Formulator's Exemption Statement

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[redacted]. Should you desire to use the cite all option for any data requirement, also include a list of the data submitters for 3-(trimethyloxysilyl) propyldimethyl octadecyl ammonium chloride.

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Please respond to this letter by **August 10, 2011** by contacting Tracy Lantz by telephone, (703) 308-6415, or by e-mail at Lantz.tracy@epa.gov or Velma Noble by telephone at (703) 308-6233 or by e-mail at Noble.velma@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Tracy Lantz

Tracy Lantz
Regulatory Team 31
Antimicrobials Division
U. S. Environmental Protection Agency
Phone: (703) 308-6415
FAX: (703) 308-8481

Kevin Kutcel

From: paygovadmin@mail.doc.twai.gov
Sent: Wednesday, June 08, 2011 10:14 PM
To: kevinkutcel@gmail.com
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 253IPPCE
Agency Tracking ID: 74208568719
Transaction Type: Sale
Transaction Date: Jun 8, 2011 10:13:33 PM

Account Holder Name: Indusco Distribution of AM Transaction Amount: $290.00 Billing Address:
1445 Jupiter Park Dr 11
City: Jupiter
State/Province: FL
Zip/Postal Code: 33458
Country: USA
Card Type: Visa
Card Number: **********2464

Decision Number:
Registration Number:
Company Name: PureShield, Inc
Company Number: 87583
Action Code: A530

Kevin Kutcel

From: DCOPPAPPS01/DC/USEPA/US@epamail.epa.gov on behalf of Pesticide Registration Improvement Act [Pesticide_Registration@epamail.epa.gov]
Sent: Wednesday, March 23, 2011 2:23 PM
To: kutcel@zoominternet.net
Subject: Waiver: Approval (75%)

March 23, 2011
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
OPP Decision Number: D-445934
EPA File Symbol or Registration Number: 87583-G Product Name: BIO PROTECT AM50 EPA
Application Receipt Date: 02-Mar-2011 EPA Waiver Request Receipt Date: 02-Mar-2011 EPA
Company Number: 87583 Company Name: PURESHIELD INC.

KEVIN KUTCEL
KRK CONSULTING LLC
PURESHIELD INC
5807 CHURCHILL WAY
MEDINA, OH 44256-

SUBJECT: Approval of Waiver Request

Dear Registrant:

The Office of Pesticide Programs has approved your request for 75% waiver of the pesticide registration fee associated with the action referenced above. The decision review period for this action will begin on the date of this letter.

The Action has been identified as Action Code: A530

ME-TOO;NEW PRODUCT;FAST TRACK;

If you have any questions, please contact Ms. ShaRon Carlisle, at (703) 308-6427.

Sincerely,

Oscar Morales, Director
Information Technology & Resources Management Division

Office of Pesticide Programs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 16, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-450575
EPA File Symbol or Registration Number: 87583-L
Product Name: BIO-PROTECT DP
EPA Receipt Date: 14-Jun-2011
EPA Company Number: 87583
Company Name: PURESHIELD INC

KEVIN KUTCEL
KRK CONSULTING LLC
PURESHIELD INC
5807 CHURCHILL WAY
MEDINA, OH 44256-

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A530
ME-TOO;NEW PRODUCT;FAST TRACK;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 6-14-11 3/23/09

Experts In-Processing Signature: B. R Date 6-16-11 Fee Paid: Yes ✓

Division management contacted on issues No_____Yes _____Date _____

EPA Reg. Number: 87583-L	EPA Receipt Date: 6-14-11

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	**yes** X	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	**yes** X	**no**			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

* No data package with this submission.
Per letter dated 03/1/2011 Registrant intends to use studies submitted by Inhold, LLC to fulfill the data requirements for this submission - please see letter for further details.

* A.I's # % Composition are available in OPP.
* CSF is approved for food.
* All essential forms are present + free of errors.
* Jacket approved.

452457
MRID: 453476
451213
lk S-4813

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. <u>All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.</u>

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.
If you have any questions on e-labels, please contact one of your division e-label experts:

AD	Willie Abney	308-1689
	Renae Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423

PROC SSING ELECTRONIC LABELS

(rev. 1/5/09, tch)

If e-label submitted via XML e-submission (not on CD-ROM), you may wish to find e-label in Documentum, save e-label to "My Documents", add e-label to ELL, start below at step 5.

Initial E-Label per application (on CD-ROM with paper via ITRMD)

1 ITRMD receives paper submission w/ e-label on CD

2 Tracking record added to OPPIN

3 ITRMD adds e-label to ELL

4 ITRMD sends paper submission to AD/BPPD/RD

5 Connect ELL record with OPPIN S#

in-process

6 Save copy of e-label from ELL to My Documents

7 Review label
(if acceptable, skip to step 20)

8 Add comments to e-label
(save; add "with comments" to filename

9 Print annotated e-label
(use "Print with Filename")

review

10 Send annotated e-label to registrant via email
(also send "How To Print")

11 File print of annotated e-label and email in jacket

12 Add annotated e-label to ELL

13 Close submission in OPPIN

out-process

Resubmission (via email to staffer or PM)

14 Receive email submission w/ e-label attached

15 Add tracking record to OPPIN

16 Add e-label to ELL

17 Connect ELL record with OPPIN S#

in-process

18 Save copy of e-labels (old & new) from ELL to My Documents

19 Compare old and new labels with Acrobat

(if revisions needed repeat steps 8-19)

review

20 Print e-label, stamp, write cover letter
(use "Print with Filename")

21 Mail stamped label & cover letter to registrant

22 File stamped label & cover letter in jacket

23 Add cover letter to ELL
(mandatory if accepted with comments)

24 Close submission in OPPIN

out-process

process - big picture
1- create OPPIN tracking
2- put label in ELL; link to S#
3- save ELL label to MyDocuments
4- compare / comment
5- outprocess

techniques to know
- filename for e-labels
- "print with filename"
- compare / comment
- printing with comments

Product ingredient source information may be entitled to confidential treatment

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
PureShield Inc. 1445 Jupiter Park, Suite 11 Jupiter, FL 33458	87583- **Product Name** Bio-Protect DP **Date of Confidential Statement of Formula** *(EPA Form 8570-4)* 08/10/2011

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

3-(trimethyloxysilyl)propyldimethyloctadecyl ammonium chloride;
Alkyl dimethyl benzyl ammonium chloride;
Octyl dimethyl ammonium chloride; Didecyl dimethyl ammonium chloride

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☑ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	**Product Name**	**Registration Number**
3-(trimethyloxysilyl)propyldimethyl octadecyl ammonium chloride Alkyl dimethyl benzyl ammonium chloride Octyl dimethyl ammonium chloride Didecyl dimethyl ammonium chloride	[redacted]	

Signature	Name and Title	Date
Kevin Kutcel	Kevin R. Kutcel / Consultant	8/10/11

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

Commercial/financial information may be entitled to confidential treatment

Inhold, LLC

June 9, 2011

U.S. Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Inhold, LLC Letter of Authorization for PureShield Inc. (Reg. No. 87583-)

To Whom It May Concern:

The following studies are owned by Inhold, LLC (company no. 70871) and this letter grants permission for PureShield Inc. (company no. 87583) to cite the following studies on their data matrices in support of the registration of their products, "Bio-Protect DP".

MRID No.	Study Title
45121301	Smith, F. (2000) AM 3651PI: Product Identity and Composition, Description of Beginning Materials, Description of Formula Process, Discussion of the Formation of Impurities, and Certified Limits. Unpublished study prepared by SciReg, Inc. 40 p.
45121302	Wells, D. (1999) AM 3651PI--Determination of Storage Stability: Lab Project Number: 13637.0897.6107.865: 13637.6107. Unpublished study prepared by Springborn Labs., Inc. 36 p.
45121303	Kuhn, J. (1999) AM 3651PI: Acute Oral Toxicity Study in Rats: Final Report: Lab Project Number: 4850-98. Unpublished study prepared by Stillmeadow, Inc. 24 p
45121304	Kuhn, J. (1999) AM 3651P: Acute Dermal Toxicity Study in Rabbits: Final Report: Lab Project Number: 4851-98. Unpublished study prepared by Stillmeadow, Inc. 22 p.
45121305	Bennick, J. (1999) AM 3651P: Acute Inhalation Toxicity Study in Rats: Final Report: Lab Project Number: 4852-98. Unpublished study prepared by Stillmeadow, Inc. 36 p.
45121306	Kuhn, J. (1999) AM 3651P: Primary Dermal Irritation Study in Rabbits: Final Report: Lab Project Number: 4854-98. Unpublished study prepared by Stillmeadow, Inc. 13 p.
45121307	Kuhn, J. (1999) AM 3651P: Primary Dermal Irritation Study in Rabbits: Final Report: Lab Project Number: 4854-98. Unpublished study prepared by Stillmeadow, Inc. 13 p.
45121308	Kuhn, J. (1999) AM 3651P: Dermal Sensitization Study in Guinea Pigs: Final Report: Lab Project Number: 4855-98. Unpublished study prepared by Stillmeadow, Inc. 18 p.
45245701	Damico, J. (2000) AM 3651P1: Physical-Chemical Characteristics. Unpublished study prepared by SciReg,Inc. 7 p
45347601	Snyder, A. (1999) AOAC Use-Dilution Method: AM 3651P: Final Study Report: Lab Project Number: 7361/SRC021099.UD: 7669/SRC061099.UD. Unpublished study prepared by ViroMed Biosafety Labs. 15 p.
45347602	Onstad, B. (2000) Germicidal and Detergent Sanitizing Action of Disinfectants: AM 3651P: Final Study Report: Lab Project Number: 7457: SRC050699.SAN. Unpublished study prepared by ViroMed Biosafety Labs. 10 p.

Please do not hesitate to contact me or our agent, Mr. Kevin Kutcel at 440-263-7305 if you should have any questions regarding this authorization.

Best Regards,

Mr. Joseph Raich

1445 Jupiter Park Dr.
Suite 11
Jupiter, FL 33458

PHONE (561) 747-5758
FAX (561) 747-5191
E-MAIL info@AM500.com
WEB SITE http://www.AM500.com

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number PureShield Inc., 1445 Jupiter Park, Suite 11, Jupiter, FL 33458 561-747-5758	EPA Registration Number/File Symbol 87583-
Active Ingredient(s) and/or representative test compound(s) 3-(Trimethoxysilyl) propyldimethyloctadecyl ammonium chloride	Date 6/8/2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) antimicrobial	Product Name Bio-Protect DP

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

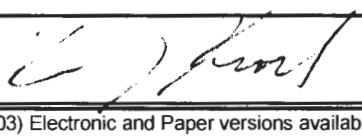
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	6/8/2011	Kevin R. Kutcel - Consultant

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 8/10/2011	EPA Reg No./File Symbol 87583-	Page 1 of 2
Applicant's/Registrant's Name & Address PureShield Inc. 1445 Jupiter Park Drive, Suite 11, Jupiter, FL 33458	Product Bio-Protect DP	

Ingredient 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride / Octyl decyl dimethyl ammonium chloride / Didecyl dimethyl ammonium chloride / Dioctyl dimethyl ammonium chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550, 830.1600, 830.1650,	Smith, F. (2000) AM 3651PI: Product Identity and	45121301	Inhold LLC 70371-21 (75497-7)	per	see permission
830.1670, 830.1750	Composition, Description of Beginning Materials,				letter
	Description of Formula Process, Discussion of the				
	Formation of Impurities, and Certified Limits. 40 p.				
830.6107	Wells, D. (1999) AM 3651PI--Determination of Storage	45121302	Inhold LLC "	per	see permission
	Stability: Lab Project Number: 13637.0897.6107.865:				letter
	13637.6107. 36 p.				
870.1100	Kuhn, J. (1999) AM 3651PI: Acute Oral Toxicity Study in	45121303	Inhold LLC "	per	see permission
	Rats. Lab Report 4850-98. 24 p.				letter
870.1200	Kuhn, J. (1999) AM 3651P: Acute Dermal Toxicity Study	45121304	Inhold LLC "	per	see permission
	in Rabbits. Lab Report 4851-98. 22 p.				letter
870.1300	Bennick, J. (1999) AM 3651P: Acute Inhalation Toxicity	45121305	Inhold LLC "	per	see permission
	Study in Rats: Lab Report 4852-98. 36 p.				letter
870.2400	Kuhn, J. (1999) AM 3651P: Primary Eye Irritation Study	45121306	Inhold LLC "	per	see permission
	in Rabbits. Lab Report 4854-98. 13 p.				letter

Signature	Name and Title	Date
	Kevin R. Kutcel - Consultant	8/10/2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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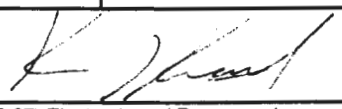
DATA MATRIX

Date 6/8/11	EPA Reg No./File Symbol 87583-	Page 2 of 2
Applicant's/Registrant's Name & Address PureShield Inc. 1445 Jupiter Park Drive, Suite 11, Jupiter, FL 33458	Product Bio-Protect DP	

Ingredient 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride / Octyl decyl dimethyl ammonium chloride / Didecyl dimethyl ammonium chloride / Dioctyl dimethyl ammonium chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2500	Kuhn, J. (1999) AM 3651P: Primary Dermal Irritation Study	45121307	Inhold LLC 70871-21	per	
	in Rabbits: Lab Report 4854-98. 13 p.				
870.2600	Kuhn, J. (1999) AM 3651P: Dermal Sensitization Study	45121308	Inhold LLC 11	per	
	in Guinea Pigs: Lab Report 4855-98. 18 p.				
830 series	Damico, J. (2000) AM 3651P1: Physical-Chemical	45245701	Inhold LLC 11	per	
	Characteristics. 7 p.				
810.2200	Snyder, A. (1999) AOAC Use-Dilution Method: AM 3651P	45347601 ✓	Inhold LLC 70871-22	per	
	Lab Number: 7361/SRC021099.UD: 7669/SRC061099.UD				
	15 p.				
810.2200	Onstad, B. (2000) Germicidal and Detergent Sanitizing	45347602 ✓	Inhold LLC 70871-22	per	
	Action of Disinfectants: AM 3651P. Lab No. 7457. 10 p.				

Signature	Name and Title	Date
	Kevin R. Kutcel - Consultant	6/8/2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

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401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 8/10/2011	EPA Reg No./File Symbol 87583-	Page 1 of 2
Applicant's/Registrant's Name & Address PureShield Inc. 1445 Jupiter Park Drive, Suite 11, Jupiter, FL 33458	Product Bio-Protect DP	

Ingredient 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride / Octyl decyl dimethyl ammonium chloride / Didecyl dimethyl ammonium chloride / Dioctyl dimethyl ammonium chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Inhold LLC	per	
			Inhold LLC	per	
			Inhold LLC	per	
			Inhold LLC	per	
			Inhold LLC	per	
			Inhold LLC	per	

Signature	Name and Title	Date
	Kevin R. Kutcel - Consultant	8/10/2011

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 6/8/11	EPA Reg No./File Symbol 87583-	Page 2 of 2
Applicant's/Registrant's Name & Address PureShield Inc. 1445 Jupiter Park Drive, Suite 11, Jupiter, FL 33458	Product Bio-Protect DP	

Ingredient 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride / Octyl decyl dimethyl ammonium chloride / Didecyl dimethyl ammonium chloride / Dioctyl dimethyl ammonium chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Inhold LLC	per	
			Inhold LLC	per	
			Inhold LLC	per	
			Inhold LLC	per	
			Inhold LLC	per	

Signature	Name and Title	Date
	Kevin R. Kutcel - Consultant	6/8/2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

KRK Consulting LLC

5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
E-mail: kutcel@zoominternet.net

March 1, 2011

US EPA (REGFEE)
Office of Pesticide Programs
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

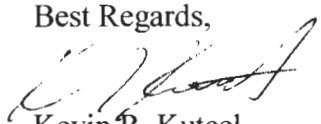
Subject: New "Me-Too" Registration for Bio-Protect DP (EPA No. 87583-)

Please accept the completed application for a new registration for the product, "Bio-Protect DP", that is a "Me-Too" to the product, "AM 3651P" (Reg. No. 70871-22) as both the CSF and label claims are identical. The product has five active ingredients on the label, all of which are from technical registered products with the EPA. The applicant has permission to cite all the data that was originally submitted by Inhold, LLC to support the cited product, Reg. No. 70871-18. Therefore, this application is citing the identical data used to support the cited product, Reg. No. 70871-22. Since this product is identical to the cited product, product chemistry has not been submitted with the application as it is relying upon the product chemistry originally submitted by Inhold, LLC, which is cited on the attached data matrices.

Within this packet, the following information is included:
1. Receipt for a payment of $290.00. This payment was based on the code, "A530" and reflects the small business waiver reduction of 75%. Also attached is a waiver approval (OPP Decision No. D-445934) showing that the US EPA approved PureShield on March 23, 2011 for a 75% waiver.
2. Letter of authorization allowing KRK Consulting LLC to represent PureShield in all matters related to the U.S. EPA.
3. Application for the "Me-Too" Registration that for "Bio-Protect AM500" that includes:
    a. 5 copies of proposed EPA Label with CD that contains pdf and doc files of proposed label.
    b. Form 8570-1 Application Form
    c. Form 8570-27 Formulator's Exemption
    d. Form 8570-4 Confidential Statement of Formula
    e. Form 8570-34 Certification with Respect to Citation of Data
    f. Form 8570-35 Data Matrix (total of 2 pages)
    g. Letter of Authorization from Inhold LLC granting PureShield Inc. permission to cite specific studies in support of proposed registration.

Your cooperation in processing this application in an expedient manner is greatly appreciated. Please call me at 440-263-7305 if you should have any questions.

Best Regards,



Kevin R. Kutcel,
Consultant for PureShield Inc.

Product ingredient source information may be entitled to confidential treatment

PURESHIELD, INC.

January 31, 2011

U.S. Environmental Protection Agency
Office of Pesticide Programs (COADR)
Document Processing Desk (7504P)
One Potomac Yard – Room S4900
2777 S. Crystal Drive
Arlington, VA 22202

RE: Authorization for Representation / Agent Status

Pursuant to 40 CFR 152.50(b)(3), we hereby designate Kevin Kutcel of KRK Consulting LLC as an Authorized Agent to act in behalf of PureShield LLC with respect to all registration matters that may come before the Agency. The address of record for all matters related to FIFRA will be:

PURESHIELD INC
c/o Kevin Kutcel
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256

Contact: Kevin Kutcel – Tel. 440-263-7305

This authorization will remain valid until further notice is given by either PURESHIELD or KRK Consulting LLC.

If you have any questions, please contact KRK Consulting LLC at 440-263-7305.

Sincerely,

Randy Wall
CFO
PURESHIELD INC

[redacted]

Cc: Kevin Kutcel – KRK

Please read instructions on reverse befor... ...pleting form. Form Appr... OMB No. 2070-0060 [Print Form]

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
PureShield, Inc. / 87583- L	Velma Noble	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
PureShield, Inc. / Bio-Protect DP	31	

5. Name and Address of Applicant *(Include ZIP Code)*

PureShield Inc.
1445 Jupiter Park, Suite 11
Jupiter, FL 33458

[X] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. 70871-22

Product Name AM 3651P

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [X] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Please accept this new registration for Bio-Protect DP that is a "Me-Too" application to Reg. No. 70871-22 "AM 3651P". Please note that both the formulation and label claims are identical. The data used to support this application is the same data, owned by Inhold LLC. Inhold LLC has granted permission for PureShield to cite this data.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[X] Yes* [ ] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [X] Plastic [ ] Glass [ ] Peper [ ] Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packeging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container		[X] On Label [ ] On Labeling accompenying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [X] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Kevin Kutcel	Consultant	440-263-7305

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Kevin Kutcel	Consultant
4. Typed Name	**5. Date**
Kevin R. Kutcel	6/8/2011

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Pages 154-155 - *Confidential Statements of Formula may be entitled to confidential treatment*